The phrase real-world data (RWD) has many definitions, depending on the source consulted; at least 4 definitions of RWD currently exist: data that are gathered outside a randomized controlled trial (RCT), data that are gathered in a noninterventional or noncontrolled setting, data that are collected in a nonexperimental setting (eg, data that are gathered as part of routine clinical care), and other data, such as data about the effectiveness of a drug in a real-world setting. The FDA has combined some of these definitions and concluded that RWD are “data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources.” Sources of RWD include electronic health records (EHRs), medical and administrative claims databases, billing records, product registries, disease registries, mobile devices, and social media.

Real-world evidence (RWE) is derived from RWD. According to the FDA, RWE is the “clinical evidence about the usage and potential benefits or risks of a medical product derived from analysis of RWD.” An International Society for Pharmacoconomics and Outcomes Research (ISPOR) and International Society for Pharmacoeconomics and Outcomes Research (ISPE) task force established to identify good practices for RWD studies defined RWE similarly, stating that RWE is “evidence obtained from analyzing RWD.” This task force further emphasized the importance of RWE by stating that it can aid in applying evidence from RCTs to decision making in healthcare and can yield insights not addressed by RCTs.

RWD can be beneficial even if it cannot be used to produce RWE. For example, RWD can assist in hypothesis generation for testing in RCTs, identification of tools for drug development (eg, biomarkers), evaluating trial feasibility, and identifying indicators of prognosis or baseline characteristics of patients for enrichment or stratification.

Multiple federal policy initiatives have led to a rise in RWD utilization and RWE generation. Among the first initiatives was the Health Information Technology for Economic and Clinical Health (HITECH) Act, which was enacted as part of the American Recovery and Reinvestment Act of 2009 (ie, the “stimulus bill”). Through its provision of incentives and support, this law has been key in promoting the use of interoperable health information technology systems and the adoption of EHRs.

SOMATULINE® DEPOT (lanreotide): INDICATIONS

SOMATULINE® DEPOT (lanreotide) injection is a somatostatin analog indicated for:

- the treatment of adult patients with unresectable, well- or moderately-differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression-free survival; and

- the treatment of adults with carcinoid syndrome; when used, it reduces the frequency of short-acting somatostatin analog rescue therapy.
A second important initiative leading to the rise of RWD and RWE utilization was the Patient Protection and Affordable Care Act of 2010. This federal law established the Patient-Centered Outcomes Research Institute (PCORI), a nonprofit corporation that was created to support the collection of validated scientific evidence to aid the United States in making informed decisions about healthcare issues. As stated on its website, PCORI accomplishes its mission by funding mainly comparative effectiveness research, specifically patient-centered outcomes research. PCORI has defined such research as that which "answers patient-centered questions, such as: 'Given my personal characteristics, conditions, and preferences, what should I expect will happen to me?'; 'What are my options and what are the potential benefits and harms of those options?'; 'What can I do to improve the outcomes that are most important to me?'; and 'How can clinicians and the care delivery systems they work in help me make the best decisions about my health and healthcare?" Patient-centered outcomes research addresses those 4 questions by evaluating the benefits and harms of healthcare interventions to aid in decision making; by considering a patient’s preferences, autonomy, and needs by focusing on outcomes of interest to the patient (eg, function, health-related quality of life [HRQoL], and survival); by including different settings and diverse subjects to assess individual differences and obstacles to implementation; and by optimizing outcomes as patient and caregiver burden, service availability, and technologic issues are addressed.

The FDA has contributed to the use of RWD by developing and implementing the Sentinel Initiative and the Framework for RWE program. Within the Sentinel Initiative program, a distributed data network consisting of the electronic health data, including administrative claims data, of more than 100 million persons is used in safety analyses to obtain evidence of the effects of medical products on patients. The Sentinel Initiative has already provided findings that have been used in regulatory decisions and that have prevented the need for postmarketing safety studies for several products.

With the enactment of the 21st Century Cures Act in 2016, the FDA developed the Framework for RWE program, which is designed to assess RWE in supporting a new indication for a drug or biologic that has already been approved or to support or satisfy requirements for postapproval studies. The FDA’s RWE program will not consider evidence from traditional clinical trials but will consider evidence generated from hybrid or pragmatic clinical trials or observational studies. A draft guidance document about the submission of RWD and RWE in support of a drug or biologic has been issued by the FDA as part of the RWE Framework program.

**From Real-World Data to Real-World Evidence**

RWE has been generated by traditional methods of outcomes research. Outcomes research is a broad discipline that often employs observational study design rather than interventional study design to understand effectiveness as opposed to efficacy. Outcomes end points can include clinical (eg, disease control), economic (eg, cost-effectiveness), or humanistic (eg, patient-reported outcomes) measures.

Because of broader heterogeneity and the lack of randomization, advanced statistical methods are an important tool in understanding the outcome in the presence of confounders and effect modifiers.

At least 2 categories of RWD studies can generate RWE about treatment effectiveness: exploratory treatment effectiveness studies and hypothesis-evaluating treatment effectiveness studies. As the name suggests, the exploratory treatment effectiveness study usually is an initial step in evaluating effectiveness and does not test a hypothesis about a particular effect of treatment or the size of such an effect. This type of study requires less preplanning than a hypothesis-evaluating treatment effectiveness study and allows changes in the study process as data become available. In contrast to the exploratory treatment effectiveness study, the hypothesis-evaluating treatment effectiveness study is designed to test a hypothesis within a particular population and thus analyze a prespecified effect, its magnitude, or both. The RWE generated from this type of study can be used with evidence from other types of studies, such as RCTs, to support recommendations regarding a specific treatment. For example, a hypothesis-evaluating treatment effectiveness study can yield RWE to show whether a treatment effect observed in multiple RCTs also occurs when the therapy is evaluated in real-world conditions, in which medication adherence is lower than in RCTs and other factors may influence effectiveness.

In general, observational studies using RWD to generate RWE do not establish causality, but can identify associations. Despite their inability to establish causality, observational studies of RWD can provide RWE of an association between treatment and an event. An example is the use of pharmacoepidemiologic safety studies (eg, observational studies of EHR data) to identify an association between a particular drug therapy and a specific adverse event (AE).

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**IMPORTANT SAFETY INFORMATION**

**Contraindications**

- SOMATULINE DEPOT is contraindicated in patients with hypersensitivity to lanreotide. Allergic reactions (including angioedema and anaphylaxis) have been reported following administration of lanreotide.
Investigating the Generation of Real-World Evidence: Why Formulary Decision Makers Should Pay Attention

**Importance of Real-World Evidence to Population Health Management and Decision Making**

The use of RWE by US payers has become common. In a survey of 19 physicians, pharmacists, and researchers from payer organizations of various sizes, 89% of participants stated that results from observational studies sometimes, often, or almost always were used within their organization. Reasons frequently mentioned for the use of RWE included safety, analysis of comparative effectiveness, and providing information that RCTs did not provide. The survey also found that 89% of participants believed that “organizations should be open to using data from observational studies as well as RCTs in making healthcare decisions.”

European countries have recognized RWE as an effective tool for accelerating drug access programs. According to a report from the 2017 Institute for Clinical and Economic Review (ICER) Membership Policy Summit, an example of accelerated access programs is the conditional reimbursement scheme that uses “commissioning through evaluation” in the United Kingdom to allow patients to access a drug that is not widely funded by the National Health Service while data about these patients’ outcomes are collected and analyzed. This approach permits patients to receive an investigational drug that appears promising but does not have adequate evidence to support its countrywide availability at the time of launch.

**CASE EXAMPLES WITH SOMATULINE® DEPOT**

To illustrate studies that have generated RWE, the following case examples with lanreotide depot (Somatuline® Depot, Ipsen) are provided. These studies were funded by Ipsen Biopharmaceuticals, Inc., the marketer of Somatuline® Depot, or its affiliates. Currently, lanreotide depot is the only FDA-approved somatostatin analogue (SSA) to treat adult patients with unresectable, well- or moderately-differentiated, locally advanced, or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression-free survival (PFS) and to treat adults with carcinoid syndrome; when used, lanreotide depot reduces the frequency of short-acting SSA rescue therapy. Somatuline® Depot is administered by a healthcare provider into the deep subcutaneous space using a prefilled syringe at a dose of 120 mg every 4 weeks. If patients are already being treated with Somatuline® Depot for GEP-NETs, healthcare providers should not administer an additional dose for carcinoid syndrome.

**Budget Impact Modeling as a Potential Indicator of Treatment Cost**

Budget impact modeling has been used to evaluate the overall costs of lanreotide depot and octreotide long-acting release (LAR) and their use in treating metastatic GEP-NETs (mGEP-NETs). At the time the analysis was conducted, the financial impact of treatment choice for mGEP-NETs was uncertain.

In this economic analysis, the model compared a base-case scenario, in which a hypothetical baseline for the utilization of lanreotide depot or octreotide LAR was considered and an alternative scenario, in which the hypothetical utilization shifted. Inputs for the model included population and epidemiologic estimates, costs of product acquisition (2017 wholesale acquisition costs) and preparation/mixing (May 2014 wage rates for a nurse in a specialty hospital and published time estimates), and treatment utilization (RWD for octreotide LAR dosages and utilization, maximum indicated dosage for lanreotide depot). The basis for these inputs was the medical literature, databases containing price information and market share data, and expert opinion. At the time of the analysis, there were no RWD regarding the lanreotide depot doses.

The base-case analysis determined the costs of using lanreotide depot or octreotide LAR to treat patients with mGEP-NETs; these costs were reported as the total cost per treated patient and were separated as costs related to product acquisition and costs related to preparation and mixing. In the alternative scenario, a shift in utilization from octreotide LAR to lanreotide depot was considered, and the incremental costs of this increase in lanreotide depot utilization were estimated.

Results from the base-case analysis showed that 313 patients with mGEP-NETs in the hypothetical cohort (N = 500) were treated with either lanreotide depot or octreotide LAR. The predicted costs per patient per year in the United States were $83,473 for lanreotide depot and $89,673 for octreotide LAR. Based on current treatment patterns (ie, 5% of patients treated with lanreotide depot and 95% treated with octreotide LAR), the model also predicted that the total cost per year per US hospital treating 500 patients with mGEP-NETs was $27,970,455. When a shift in utilization as proposed in the alternative scenario (ie, 30% of patients treated with lanreotide depot and 70% treated with octreotide LAR), the estimated annual total cost per US hospital was $27,481,840; such a shift in product utilization would be expected to result in a cost savings of $488,615 per hospital per year (Table 1). Use of lanreotide depot led to cost savings that were

**IMPORTANT SAFETY INFORMATION (continued)**

**WARNINGS AND PRECAUTIONS**

- **Cholelithiasis and Gallbladder Sludge**
  - SOMATULINE DEPOT may reduce gallbladder motility and lead to gallstone formation.
  - Periodic monitoring may be needed.
  - If complications of cholelithiasis are suspected, discontinue SOMATULINE DEPOT and treat appropriately.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.
associated with variation in acquisition prices among different products and their widely used doses and the lower cost of preparing and mixing lanreotide depot. One-way sensitivity analyses determined that the results were most sensitive to the proportions of patients who received more than the maximum indicated dose of octreotide LAR (ie, dosages > 30 mg every 4 weeks) and the acquisition costs of both products. If the octreotide LAR dose was assumed to be the maximum indicated, the shift in utilization was expected to lead to an increase of $878,489 in total costs per US hospital per year.†

Importance of Real-World Data in Budget Impact Modeling

The use of RWD in this modeling study had an important impact on the economic findings. By including the RWD regarding the reported use of greater-than-maximum-indicated doses of octreotide LAR by patients with mGEP-NETs in the base-case assumption, the model showed an annual cost savings of more than $400,000 per US hospital when lanreotide depot utilization increased from its current 5% rate to 30%. However, this savings with increased lanreotide depot utilization would not have been recognized if only the maximum indicated dose of octreotide had been included in the analysis. When the maximum indicated doses of octreotide LAR and lanreotide depot were included in the model, the shift to lanreotide depot increased, not decreased, annual costs per hospital. The economic impact of the RWD obtained from clinical practice is particularly important in light of the higher prevalence of GEP-NETs as a result of increased diagnosis rates and relatively long survival times.†

Limitations of Budget Impact Modeling

The model is based on assumptions of RWD for product utilization; therefore, the model may not guarantee the predicted annual savings. In addition, the use of the maximum indicated dose of lanreotide depot by all patients was assumed. Because head-to-head trial data and comparative effectiveness between the 2 SSAs are lacking, costs based on treatment response or costs after treatment discontinuation were not included in the model. These analyses also did not include indirect costs, such as those that result from productivity losses, time losses, and transportation. Cost assumptions included in the analysis may have changed over time.†

Real-World Assessments of Progression-Free Survival

A prospective, observational study (NCT02730104), still in process as of the date of this publication, is assessing clinically defined PFS estimates for patients with locally advanced mGEP-NETs treated with lanreotide depot in a real-world setting. This study, which includes a 24-month observation period that begins with the start of lanreotide depot treatment, had a preplanned interim analysis of survival and clinically defined PFS for the first 50 patients who had 1 year of follow-up during treatment or had an event (ie, disease progression or death). Inclusion criteria were age at least 18 years; diagnosis of locally advanced or metastatic well-differentiated NETs of the small intestine, stomach, colon/rectum, or pancreas; treatment with lanreotide depot/autogel; and an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2. Exclusion criteria included diagnosis of poorly differentiated or high-grade GEP-NETs or tumors of unknown grade.†

The median age of the first 50 patients with 1 year of follow-up was 65 years; most patients (84%) were Caucasian, and most (96%) had an ECOG performance status of 0 or 1. More than one-third of patients (36%) had received prior treatment with octreotide LAR.†

At 12 months, the PFS estimate (primary outcome) was 91.7% (Figure 1).† During the year of follow-up, 6 patients (12%) had died or experienced disease progression.†

Table 1. Results of Base-Case Analysis†a,b

<table>
<thead>
<tr>
<th>Drug/Cost</th>
<th>Initial Scenario</th>
<th>Comparison Scenario</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lanreotide depot</td>
<td>$1,305,686</td>
<td>$7,834,115</td>
</tr>
<tr>
<td>Octreotide LAR</td>
<td>$26,664,769</td>
<td>$19,647,725</td>
</tr>
<tr>
<td><strong>Total Costs</strong></td>
<td><strong>$27,970,455</strong></td>
<td><strong>$27,481,840</strong></td>
</tr>
<tr>
<td><strong>Difference in Total Costs</strong></td>
<td><strong>$488,615</strong> ****</td>
<td><strong>$488,615</strong> ****</td>
</tr>
</tbody>
</table>

LAR indicates long-acting release.

*aUtilization defined as market share at the time of the analysis; comparison scenario is the hypothetical change in market share.

*bCosts include those for drugs and their mixing and administration.

†Difference indicates the change in total costs between the baseline and comparison year. Cost savings in a comparison year are indicated by negative numbers.


IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

- **Hypoglycemia or Hyperglycemia**
  - Patients treated with SOMATULINE DEPOT may experience hypoglycemia or hyperglycemia.
  - Blood glucose levels should be monitored when SOMATULINE DEPOT treatment is initiated, or when the dose is altered, and antidiabetic treatment should be adjusted accordingly.
Investigating the Generation of Real-World Evidence: Why Formulary Decision Makers Should Pay Attention

The most frequently reported AEs were nausea (6%), fatigue (4%), and abdominal pain (4%). The AEs that were most frequently cited as the cause for discontinuation were hypoglycemia (2%) and pneumonitis (2%).

Importance of Real-World Data in the Study of Progression-Free Survival

As stated previously, real-world clinical outcomes often can provide more generalizable results compared with controlled trials. This interim analysis of this observational study has provided the first prospectively collected real-world outcomes of lanreotide depot treatment of GEP-NETs. These results suggest that treatment with lanreotide depot/autogel is effective in controlling GEP-NETs and that patients are generally satisfied with this therapy.

Limitation of Real-World Assessment of Progression-Free Survival

A limitation of this study was the use of a convenience sample from the US Oncology patient population; therefore, the generalizability of these findings may not be widely applicable to other populations. In addition, the limited duration of the interim analysis (ie, 1 year) may be insufficient to detect progressive events in the indolent disease of GEP-NETs.

Real-World Insight Into Treatment Experience Among Clinicians

To learn how RWD can provide insight into healthcare efficiency, Ryan and colleagues conducted a prospective, nonrandomized, noninterventional time and motion study of patients treated with either lanreotide or octreotide LAR at 5 cancer centers in the United States.

Of the 44 patients enrolled in the study, 22 patients were in the lanreotide group and 22 were in the octreotide group. Treatment was administered every 4 weeks, with median dosages of 120 mg for lanreotide and 30 mg for octreotide LAR. Patients were excluded from the study if they were being treated with either medication as part of a clinical trial or if more than 1 injection was needed to administer the total drug dose (ie, >120 mg lanreotide; >30 mg octreotide LAR).

Nurses prepared and administered the majority of doses for both lanreotide and octreotide LAR (Table 2). Significantly more doses of lanreotide were prepared in the medication room compared with octreotide LAR (63.6% vs 13.6%; \( P = .002 \)). Although not statistically significant, doses of octreotide LAR were more likely to be prepared at the patient’s bedside than doses of lanreotide (45.4% vs 27.3%). No instances of clogging, drug wastage, device issues, or acute AEs were reported in either group, and there were no systematic differences among the materials and supplies provided to prepare doses.

The study results indicated that the mean preparation time required for lanreotide was significantly shorter than for octreotide LAR (1.38 min vs 5.0 min; \( P < .001 \)). Likewise, the total time for drug delivery (determined as the total time for preparation and administration) was significantly less for lanreotide (2.5 min vs 6.2 min; Table 2).

<table>
<thead>
<tr>
<th>Summary of Clinically Defined Progression-Free Survival</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Patients</strong></td>
</tr>
<tr>
<td>-------------------</td>
</tr>
<tr>
<td>50</td>
</tr>
<tr>
<td><strong>Patients at Risk</strong></td>
</tr>
<tr>
<td><strong>% Estimated Survival (95% CI)</strong></td>
</tr>
</tbody>
</table>

CI indicates confidence interval; PD, progressive disease.


IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

- Cardiovascular Abnormalities
  - SOMATULINE DEPOT may decrease heart rate.
  - In patients without underlying cardiac disease, SOMATULINE DEPOT may lead to a decrease in heart rate without necessarily reaching the threshold of bradycardia.
  - In patients suffering from cardiac disorders prior to treatment, sinus bradycardia may occur. Care should be taken when initiating treatment in patients with bradycardia.
P \(<.001\); however, the average time required to administer the drug was not significantly different between groups. There was wide variation in the total time required for drug delivery (Figure 2).\(^{19}\)

Compared with staff members who administered octreotide LAR, staff members who administered lanreotide reported greater product satisfaction (5.0 vs 4.0, respectively, where 1 = not satisfied and 5 = very satisfied; \(P = .03\)). Furthermore, there was a significant difference in reported stress levels related to the need to avoid needle clogging (\(P = .034\)) and concerns over device failure (\(P = .057\)), with the use of lanreotide being associated with lower stress levels related to these factors compared with octreotide LAR. Conversely, reported stress levels related to causing pain to the patient during the injection were higher for lanreotide (\(P = .025\)).\(^{19}\)

**Importance of Real-World Data in Treatment Experience**

The implementation of a product into a clinic workflow is a practical consideration formulary decision-makers may weigh when considering a product for inclusion in a hospital formulary. RWD can provide insight into differences in product characteristics that may impact healthcare staff involved in the preparation and administration of the product.\(^{19}\)

As the numbers of patients diagnosed with cancer in the United States grows,\(^{20}\) frontline healthcare clinicians charged with the care of these patients may become increasingly strained. Nurses, in particular, have expressed concern over time constraints and the inability to spend adequate time with patients. The results of a 2009 international survey of 2203 nurses from 11 countries indicated that...
92% experienced time constraints that prevented them from spending what they perceived as enough time with their patients.21

Therapies that improve operational efficiency while decreasing drug delivery time and stress on clinicians may be desirable. Satisfaction scores reported by staff members involved in drug administration in this study indicated a preference for lanreotide, which was shown to be related to ease of use, less concern of clogging and device failures, as well as decreased preparation time.19

Limitations of Real-World Data in Treatment Experience

Several limitations were identified in this study. Because patients were not randomly assigned to groups, patient and clinic variables such as disease duration and performance status were not balanced between groups. Furthermore, no adjustment for multiplicity was made, though multiple statistical comparisons were made. Total cost of care and cost effectiveness of treatments were not considered in this study and incorporation of these parameters would require a full pharmacoeconomic analysis. Because patients received no follow-up, no long-term AE information was collected. Additionally, healthcare personnel may have changed their behavior as a result of being observed. Finally, because data were obtained from 5 cancer centers in the United States, these results may not be generalizable to other clinics.19

Real-World Insight Into Treatment Patterns

To gain insight into the real-world patient characteristics and treatment of mGEP-NETs, a retrospective observational study of a commercial administrative claims database and supplemental chart review were conducted. The database was the Pharmaceutical Research Associates (PRA) Health Sciences US Outpatient Medical and Prescription Claims database, which is a multiple-platform source of an estimated 600 million claims annually submitted for 180 million patients.22

Eligibility criteria for the study were at least 18 years of age at diagnosis, at least 1 claim for mGEP-NETs during the study period (January 1, 2014–December 31, 2016), treatment with either lanreotide depot or octreotide LAR during the index period (period from the index date to the discontinuation of the SSA), and at least 12 months of data after the index date (the date of the earliest claim for an SSA that was on or after the date of a claim for metastatic disease). Patients were excluded from the study if their records showed evidence of their participation in a clinical trial.22

Of the 2900 patients with 1 or more claims for NETs in the database, 108 patients treated with lanreotide depot and 440 patients treated with octreotide LAR met the eligibility criteria.22

The demographic characteristics of patients in the 2 treatment groups were similar: the mean age of patients at the start of therapy was 61.5 years for those treated with lanreotide depot and 62.8 years for those treated with octreotide LAR; approximately 50% of patients in each treatment group were female; hypertension and type 2 diabetes affected approximately 50% and 25% of patients, respectively, in each treatment group; and the liver was the most common site of metastases. The occurrence of carcinoid syndrome differed between the 2 groups, being more frequently found in patients treated with octreotide LAR than in those treated with lanreotide depot (39.8% vs 11.1%; P = .02).22

The first-line treatment for mGEP-NETs in 93.5% of patients treated with lanreotide depot and 92.5% of patients treated with octreotide LAR was an index SSA. Only 1 patient (1.1%) was treated with more than the maximum indicated dosage of lanreotide depot (maximum indicated dosage, 120 mg every 4 weeks), whereas 47 patients treated with octreotide LAR received greater than the maximum indicated dosage (maximum indicated dosage, 30 mg every 4 weeks, P < .01). After treatment with the index SSA, the most common treatments were lanreotide depot for patients initially treated with octreotide LAR and locoregional intervention for patients initially treated with lanreotide depot (Table 3).22

Importance of Real-World Data in the Study of Treatment Patterns

Treatment dosing patterns can be a key indicator into utilization and budget costs at a population level. Previous RWE studies among patients with NETs treated with octreotide LAR observed dose escalation of 17% to 38% beyond the maximum indicated dose of 30 mg every 4 weeks through dosage increase or frequency reduction.25–26 However, the date of data collection for those studies was before 2012, when treatment options were limited. With the availability of more treatment options in the clinical armamentarium, there was a need to understand how patterns and utilization changed over time.

This study was the first to obtain RWE regarding the patterns of treatment after the approval of lanreotide depot for patients with

IMPORTANT SAFETY INFORMATION (continued)

Drug Interactions

• SOMATULINE DEPOT may decrease the absorption of cyclosporine (dosage adjustment may be needed); increase the absorption of bromocriptine; and require dosage adjustment for bradycardia-inducing drugs (e.g., beta-blockers).
mGEP-NETs in the United States. The study also showed that guideline recommendations for the use of SSAs as first-line therapy for mGEP-NETs are being followed in community practice in the United States, and dose escalation was more frequent among patients treated with octreotide LAR.22

Limitations of the Study of Real-World Treatment Patterns

Limitations of this study included its retrospective design and small sample sizes. Misclassification of data due to errors or omissions may have happened, and key variables such as survival and primary tumor type were unavailable in the claims analysis. It is also possible that the treatment patterns of lanreotide depot shortly after its market introduction may have differed from its treatment patterns in later periods.22

CONCLUSIONS

RWE can provide insights beyond those of clinical trials with generalizable findings. These insights are important for population health management. Future advancements in structured data capture and analytic approaches are needed.●

Acknowledgements

Medical writing support provided by Julia C. Jones, PharmD, PhD, MWC, ELS.

REFERENCES


IMPORTANT SAFETY INFORMATION (continued)

Special Populations

• Lactation: Advise women not to breastfeed during treatment and for 6 months after the last dose.

To report SUSPECTED ADVERSE REACTIONS, contact Ipsen Biopharmaceuticals, Inc. at 1-855-463-5127 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.