BILLING CODE: 4140-01-P

DEPARTMENT: DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health

ACTION: Notice

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing and/or co-development in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing and/or co-development.

ADDRESSES: Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD, 20850-9702.

FOR FURTHER INFORMATION CONTACT: Information on licensing and co-development research collaborations, and copies of the U.S. patent applications listed below may be obtained by contacting: Attn. Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD, 20850-9702, Tel. 240-276-5515 or email ncitechtransfer@mail.nih.gov. A signed Confidential Disclosure Agreement may be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

Title of invention:

Method for Purifying Antibodies

Description of Technology:

This technology is a method for purifying a biologic composition, comprising diafiltering the biologic composition into a composition comprising phosphate buffered saline (PBS) to obtain a purified composition. The method is particularly useful for removing one or more impurities from the biologic composition, such as bis(2-hydroxyethyl)amino-tris(hydroxymethyl)methane (Bis-tris).The technology is directed to large scale manufacturing of Chimeric 14.18 (Ch14.18) monoclonal antibodies. Ch14.18 is an anti-GD_2 monoclonal antibody and has been described in Gillies *et al.*, *Journal of Immunological Methods* 125:191-202 (1989).

Potential Commercial Applications:

- Large scale manufacturing of chimeric monoclonal antibodies

Value Proposition:

- Cost effective means of removing impurities to produce GMP grade chimeric antibodies for regulatory approval.

Development Stage:

Clinical Phase II, FDA/EMA approved Chemistry, Manufacturing and Controls (CMC) large scale manufacturing to produce GMP grade chimeric antibodies

Inventor(s):

David A. Meh (United Therapeutics Corporation), Timothy Atolagbe (United Therapeutics Corporation), G. Mark Farquharson (United Therapeutics Corporation), Samir Shaban (National Cancer Institute), Mary Koleck (National Cancer Institute), George Mitra (National Cancer Institute)

Intellectual Property:

HHS Ref. No. E-291-2014/0-US-01, corresponding to US Provisional Patent App. No. 62/028,994, filed July 25, 2014, entitled "Method for Purifying Antibodies using PBS"
HHS Ref. No. E-291-2014/0-US-02, corresponding to US Patent App. No. 14/809,211, filed July 25, 2015, entitled "Method for Purifying Antibodies using PBS"
HHS Ref. No. E-291-2014/0-PCT-03, corresponding to International Patent App. No. PCT/US2015/042241, filed July 27, 2015, entitled "Method for Purifying Antibodies"

Publications:

1. FDA published document: http://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/125516Orig1s000TOC.cfm
2. US Food and Drug Administration. FDA approves first therapy for high-risk neuroblastoma.http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm437460.htm
3. WO2016015048 METHOD FOR PURIFYING ANTIBODIES https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2016015048

Contact Information:

Requests for copies of the patent application or inquiries about licensing, research collaborations, and co-development opportunities should be sent to John D. Hewes, Ph.D., email: john.hewes@nih.gov.

Dated: May 11, 2016

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John D. Hewes

Technology Transfer Specialist, Technology Transfer Center, National Cancer Institute

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