REYATAZ is a protease inhibitor indicated for use in combination with other antiretroviral agents for the treatment of human immunodeficiency virus (HIV–1) infection in patients 3 months and older weighing at least 10 kilograms.

In a letter dated August 19, 2014, Bristol-Myers Squibb notified FDA that REYATAZ (atazanavir sulfate) capsules, 100 mg, had been discontinued. The REYATAZ 150-, 200-, and 300-mg capsule strengths continue to be marketed by Bristol-Myers Squibb. The 100-mg dosage strength of this drug product is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Lachman Consultant Services, Inc., submitted a citizen petition dated July 7, 2014 (Docket No. FDA–2014–P–0980), under 21 CFR 10.30, requesting that the Agency determine whether REYATAZ (atazanavir sulfate) capsules, 100 mg, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that REYATAZ (atazanavir sulfate) capsules, 100 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that REYATAZ (atazanavir sulfate) capsules, 100 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of REYATAZ (atazanavir sulfate) capsules, 100 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that the product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list REYATAZ (atazanavir sulfate) capsules, 100 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to REYATAZ (atazanavir sulfate) capsules, 100 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: December 30, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–30909 Filed 1–5–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Her2 Monoclonal Antibodies, Antibody Drug Conjugates, and Site Specific Antibody Conjugate Methods for the Treatment of Cancer

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR part 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to HUIYU Pharmaceuticals Co, Ltd located in Neijiang City, CHINA to practice the inventions embodied in U.S. Provisional Patent Application 61/833,732, filed June 11, 2013 entitled ''Her2-Specific Monoclonal Antibodies and Conjugates Thereof'' [HHS Ref. No.: E–351–2013/0–US–01], and International Application PCT/US2014/041492, filed June 9, 2014 entitled ''Her2-Specific Monoclonal Antibodies and Conjugates Thereof'' [HHS Ref. No.: E–351–2013/0–PCT–02], any PCT, US or foreign applications claiming the benefit of. The patent rights in these inventions have been assigned to the Government of the United States of America.

The prospective exclusive license territory may be limited to China, and the field of use may be limited to:

The use of the m860 monoclonal antibodies as mono-specific antibodies; or targeting moieties for immunoconjugates, wherein the antibodies are conjugated to auristatin F and analogues thereof, for the treatment of HER2 positive cancers.

DATES: Only written comments or applications for a license (or both) which are received by the NIH Office of Technology Transfer on or before February 5, 2015 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Eggerton Campbell, Ph.D. Licensing and Patenting Manager, Cancer Branch, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–5282; Facsimile: (301) 435–4013; Email: *Eggerton.Campbell@nih.gov.*

SUPPLEMENTARY INFORMATION: These inventions concern Antibody Drug Conjugates (ADCs). ADCs can demonstrate high efficacy as cancer therapeutics, however, much more can be done to improve their efficacy and safety profile. Site-specific antibody drug conjugation is a promising way to do this.

The scientists at the NIH have identified a fully human monoclonal antibody, m860, that binds to cell surface-associated Her2 with affinity comparable to that of Trastuzumab (Herceptin) but to a different epitope. In addition, the scientist developed a site-specific glycan engineering method to conjugate the antibody to the small molecule drug auristatin F. The ADC prepared though this site-specific approach shows very good stability, cell surface binding activity and also potent specific cell killing activity against Her2 positive cancer cells, including Trastuzumab resistant breast cancer cells. This ADC has the potential to be developed as a targeted therapeutic for Her2-overexpressing cancers.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license may be granted unless the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404 within thirty (30) days from the date of this published notice.

Applications for a license in the field of use that are filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: December 30, 2014.

Richard U. Rodriguez,

Acting Director, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2014–30878 Filed 1–5–15; 8:45 am]

BILLING CODE 4140–01–P