YmAbs Granted Rare Pediatric Disease Designation for hu3F8 Antibody

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The FDA grants Y-mAbs Therapeutics, Inc. a Rare Pediatric Disease Designation for hu3F8 for the treatment of Neuroblastoma

NEW YORK, July 5, 2017 – Y-mAbs Therapeutics, Inc. (YmAbs), an immunotherapy company discovering and developing innovative treatments for patients with cancer, today announced that it has been granted a Rare Pediatric Disease Designation by the FDA for hu3F8, a monoclonal antibody for the treatment of Neuroblastoma.

"YmAbs continues to focus on maximizing its portfolio of rare pediatric disease assets" said Thomas Gad, Founder, Executive Chairman and President of YmAbs."

Dr. Claus Møller, Chief Executive Officer further notes, "We are committed to bringing hu3F8 to children diagnosed with Neuroblastoma, a life-threatening cancer with a clear unmet medical need. We are very pleased with the designation granted by the FDA."

About Rare Pediatric Disease Program:

In 2012, the United States Congress effectuated a Rare Pediatric Disease Priority Review Voucher Program to incentivize pharmaceutical sponsors to develop drugs for rare pediatric diseases. A sponsor who obtains approval of a new drug application (NDA) or biologics license application (BLA) for a rare pediatric disease may be eligible for a Priority Review Voucher (PRV), which may be redeemed to obtain priority review for a marketing application by the owner of such PRV. A PRV is fully transferrable and can be sold to any sponsor, who in turn can redeem the PRV for priority review of a marketing application in six months, compared to the standard timeframe of approximately ten months. In December 2016, the House of Representatives has approved the 21st Century Cures Act, which among other initiatives reauthorizes the Priority Review Voucher (PRV) program for rare pediatric diseases until 2020. A drug that receives a Rare Pediatric Disease Designation (RPDD) before October 1, 2020 continues to be electable for a voucher if the drug is approved before October 1, 2022.

About YmAbs:

YmAbs is a clinical stage biopharmaceutical company focused on developing new cancer treatments through immunotherapies. In addition, YmAbs utilizes its platform technologies to create next-generation humanized, affinity matured bispecific antibodies targeting GD2 and B7H3. To further improve our bispecific antibodies, we are collaborating on the development of a novel human protein tag that dimerizes T-cell engaging bispecific antibodies, which enables higher tumor binding and results in a longer serum half-life and a significantly greater T-cell mediated killing of tumor cells. Our treatments could potentially reduce longer-term toxicities associated with current chemotherapeutics and provide the potential for curative therapy even for patients with widespread disease. YmAbs' goal is to drive multiple product candidates in select solid tumor cancers to FDA licensure. Each candidate has the potential to treat a variety of high-risk cancers.

To learn more, visit www.ymabs.com

SOURCE:

Y-mAbs Therapeutics, Inc.

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