

AB2 Bio and WuXi Biologics Announce Collaboration to Accelerate Commercial-Scale Manufacturing of Tadekinig alfa

- **Tadekinig alfa is a novel IL-18 binding protein in pivotal Phase 3 testing for orphan disease IL-18 driven monogenic Hemophagocytic Lymphohistiocytosis (HLH)**
- **WuXi Biologics to undertake commercial scale manufacturing to support U.S. market launch**

Lausanne, Switzerland, and Shanghai, China, October 29, 2020 — AB2 Bio Ltd., a Swiss advanced clinical-stage biotech company developing innovative therapies for the treatment of severe systemic autoinflammatory diseases, and WuXi Biologics (“WuXi Bio”) (2269.HK), a global company with leading open-access biologics technology platforms, today announced that they have entered into a collaboration to set-up and accelerate commercial-scale manufacturing of Tadekinig alfa, AB2 Bio’s novel recombinant IL-18 binding protein.

Per the agreement, AB2 Bio is in the process of transferring manufacturing of Tadekinig alfa to WuXi Biologics, where commercial scale manufacturing will be conducted. AB2 Bio will prepare the submission of the license application to the U.S. Food and Drug Administration (FDA) and initiate commercialization activities, including scaling-up manufacturing, leveraging WuXi Biologics’ unparalleled services and capabilities.

The pivotal Phase 3 trial with Tadekinig alfa in primary, monogenic HLH, is expected to read-out in mid-2021, after which the Biologics License Application (BLA) application process will be initiated. Monogenic HLH is a rare, life-threatening disease that occurs in infants and young children, characterized by hyperinflammation due to an overactivated immune system. There are currently no drugs specifically approved to treat IL-18 driven monogenic HLH and severe inflammatory conditions, disability and death are common outcomes.

Michael Soldan, CEO of AB2 Bio commented: “We are eager to progress Tadekinig alfa to the market, and our manufacturing agreement with WuXi Biologics will accelerate commercial scale production, taking critical steps towards bringing Tadekinig alfa to patients. We are now focused on completing enrolment of the ongoing pivotal trial of Tadekinig alfa in primary HLH patients and expect to announce topline results in mid-2021. In parallel, we are preparing to file for marketing authorization in the U.S. to bring this product as soon as possible to primary, monogenic HLH patients. Tadekinig alfa has demonstrated to be an effective and safe treatment, changing the lives of the very young patients suffering from this devastating condition.”

Dr. Chris Chen, CEO of WuXi Biologics commented: “We’re excited to be AB2 Bio’s valued partner in the commercial-scale manufacturing of Tadekinig alfa. From our perspective, this collaboration is a direct result of our Win-the-Molecule strategy to attract customers based on our cutting-edge technology, best timeline, excellent track record and unparalleled capacity throughout the development cycle. We are committed to the swift delivery of high-quality products and services to customers and, as a result, making life-saving treatments accessible to patients around the world.”

Beyond primary HLH, Tadekinig alfa has potential to be developed as a pipeline-in-a-product for indications where high IL-18 levels play a key role in disease pathology, including other autoinflammatory orphan conditions, oncology and infectious diseases, such as [COVID-19](#)¹.

About Tadekinig alfa

Tadekinig alfa is a novel, recombinant human interleukin-18 binding protein (IL-18 BP) inhibiting IL-18, a major proinflammatory cytokine. The Company is developing a pipeline-in-a-product opportunity with Tadekinig alfa in a wide range of IL-18 mediated diseases where hyperinflammation or ‘cytokine storm’, is an issue, including COVID-19. Tadekinig alfa is currently in late-stage development for the treatment of severe orphan autoinflammatory diseases, including primary and secondary HLH and Still’s disease. Tadekinig alfa has obtained EMA’s Orphan Drug Designation and U.S. FDA’s Orphan Drug Designation, Breakthrough Therapy and Pediatric Rare Disease Designations, making it eligible for a Priority Review Voucher

About Hemophagocytic Lymphohistiocytosis (HLH)

HLH is a group of rare life-threatening diseases that usually occurs in infants and young children, who mostly inherit the disease (“primary, familial, genetic HLH”). HLH may also occur in children and adults complicating the course of other conditions, i.e. rheumatic diseases, viral infections, chemotherapy, can cause HLH (“secondary HLH”). It is characterized by hyperinflammation due to an overactivated immune system. Fever and an enlarged spleen are the most common symptoms of the disease. People with HLH usually develop symptoms within the first few months or years of life, and if left untreated, patients with HLH die within a few months due to progressive multi-organ failure. There is a high unmet need for novel treatment options that are safe and that can effectively stop disease progression.

About AB2 Bio Ltd

AB2 Bio is an advanced clinical-stage biotech company developing innovative therapies for the treatment of severe systemic autoinflammatory diseases, including rare diseases with high unmet medical needs. AB2 Bio is building a late-stage clinical pipeline with Tadeking alfa, a novel IL-18 binding protein with established clinical proof-of-concept in three, life-threatening orphan autoinflammatory indications. The Company is also advancing Tadekinig alfa in preclinical development in oncology and COVID-19 cytokine release syndrome. AB2 Bio is located in the Innovation Park at the Ecole Polytechnique Fédérale de Lausanne (EPFL), Switzerland. More information can be found on www.ab2bio.com.

About WuXi Biologics

WuXi Biologics (stock code: 2269.HK), a Hong Kong-listed company, is a leading global open-access biologics technology platform offering end-to-end solutions to empower organizations to discover, develop, and manufacture biologics from concept to commercial manufacturing. The company’s history and achievements demonstrate its commitment to providing a truly ONE-stop service offering and strong value proposition to its global clients. As of June 30, 2020, there were a total of 286 integrated projects, including 141 projects in pre-clinical development stage, 125 projects in early-phase (phase I and II) clinical development, 19 projects in late-phase (phase III) development and one project in commercial manufacturing. With total estimated capacity for biopharmaceutical

¹ Lucas *et al.*, Nature July 2020, 584, pages 463–469



production planned in China, Ireland, the U.S., Germany, and Singapore exceeding 280,000 liters after 2023, WuXi Biologics will provide its biomanufacturing partners with a robust and premier-quality global supply chain network. For more information on WuXi Biologics, please visit: www.wuxibiologics.com.

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