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# Prime Therapeutics and Takeda agree to outcomes-based arrangement for Hemophilia A treatment ADVATE® [Antihemophilic Factor (Recombinant)]

*Agreement takes into account total cost of care, including emergency department visits*

EAGAN, Minn. – Dec. 16, 2020 – In an effort to help assess the value of hemophilia A treatments relative to total health care costs and emergency department visits, Prime Therapeutics LLC (Prime) has finalized an arrangement with Takeda Pharmaceuticals America, Inc., a wholly-owned subsidiary of Takeda Pharmaceutical Company Limited (TSE: 4502/NYSE:TAK) ("Takeda") for the factor replacement product ADVATE® [Antihemophilic Factor (Recombinant)], which is used in the treatment and prevention of bleeding episodes in patients with hemophilia A (congenital factor VIII deficiency).

Hemophilia treatment options have increased in recent years, including innovative therapies. However, these innovations come at a high price. Therefore, it is important to establish integrated medical and pharmacy benefit contracts between payers and product manufacturers on existing treatments. The arrangement between Prime and Takeda provides:

- an opportunity to assess clinical outcomes and cost implications with an existing treatment for hemophilia A,
- a health plan remuneration model based on the level of certain quantifiable medical costs associated with unsuccessful treatment under a total cost of care model.

Hemophilia is a bleeding disorder that results from a lack of the essential clotting protein called factor VIII.[1] About 80 percent of the approximate 18,000 people living with hemophilia in the United States have hemophilia A.[2] Arrangements such as this help Prime better evaluate what treatments may provide the best outcomes at the best costs for members and health plan clients.

"Our work since pioneering such contracts over a decade ago has been targeted and intentional – and this agreement with Takeda is no different," said Kelly McGrail-Pokuta, vice president of trade relations and strategy and chief trade relations officer at Prime. "Members with hemophilia need treatments that work for them at a reasonable price, and that's exactly what drives this collaboration."

"Takeda has a rich heritage of serving patients and providing innovative medicines to those who need them. This agreement with Prime will help us continue to deliver on our promise to provide critically important treatments with personalized care approaches to fit each patient's needs, and to demonstrate the treatment's overall value," said Richard Ascroft, senior vice president managed markets and patient services at Takeda.

1. National Hemophilia Foundation. "Fast Facts." National Hemophilia Foundation website. Available here: https://www.hemophilia.org/About-Us/Fast-Facts. Last accessed October 2020.
2. National Hemophilia Foundation. "Frequently Asked Questions About Hemophilia." National Hemophilia Foundation website. Available here: https://www.hemophilia.org/walk/docs/NHFFAQs.pdf Last accessed October 2020.

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**About Prime Therapeutics**
Prime Therapeutics LLC (Prime) makes health care work better by helping people get the medicine they need to feel better and live well. Prime provides total drug management solutions for health plans, employers, and government programs including Medicare and Medicaid. The company processes claims and offers clinical services for people with complex medical conditions. Prime serves more than 30 million people. It is collectively owned by 18 Blue Cross and Blue Shield Plans, subsidiaries or affiliates of those plans. For more information visit www.primetherapeutics.com or follow @Prime_PBM on Twitter.

**ADVATE Professional Important Information**
**About ADVATE [Antihemophilic Factor (Recombinant)]**
**Indications**
ADVATE is a recombinant antihemophilic factor indicated for use in children and adults with hemophilia A (congenital factor VIII deficiency) for:

- Control and prevention of bleeding episodes.
- Perioperative management.
- Routine prophylaxis to prevent or reduce the frequency of bleeding episodes.

ADVATE is not indicated for the treatment of von Willebrand disease.

**DETAILED IMPORTANT RISK INFORMATION**

**CONTRAINDICATIONS**
Patients who have life-threatening hypersensitivity reactions, including anaphylaxis, to mouse or hamster protein or other constituents of the product.

**WARNINGS & PRECAUTIONS**
**Hypersensitivity Reactions**
Allergic-type hypersensitivity reactions, including anaphylaxis, have been reported with ADVATE. Symptoms include dizziness, paresthesia, rash, flushing, facial swelling, urticaria, dyspnea, pruritus, and vomiting. Discontinue ADVATE if hypersensitivity symptoms occur and administer appropriate emergency treatment.

**Neutralizing Antibodies**
Neutralizing antibodies (inhibitors) have been reported following administration of ADVATE predominantly in previously untreated patients (PUPs) and previously minimally treated patients (MTPs). Monitor all patients for the development of factor VIII inhibitors by appropriate clinical observation and laboratory testing. If expected plasma factor VIII activity levels are not attained, or if bleeding is not controlled with an expected dose, perform an assay that measures factor VIII inhibitor concentration.

**ADVERSE REACTIONS**

- Serious adverse reactions seen with ADVATE are hypersensitivity reactions, including anaphylaxis, and the development of high-titer inhibitors necessitating alternative treatments to factor VIII.

- The most common adverse reactions observed in clinical trials (>5% of subjects) were pyrexia, headache, cough, nasopharyngitis, arthralgia, vomiting, upper respiratory tract infection, limb injury, nasal congestion, and diarrhea.

**Click here for Full Prescribing Information:**
https://www.shirecontent.com/PI/PDFs/ADVATE_USA_ENG.pdf

**About Hemophilia**
Hemophilia is a chronic disease that causes longer-than-normal bleeding due to absent or deficient clotting factor in the blood.[1] In 2018, hemophilia A affects about 158,225 people worldwide, whereas hemophilia B affects about 31,247 people worldwide.[5] People with hemophilia, working closely with their healthcare professionals, can live healthy lives with proper care and adequate treatment. Treatment regimens typically include on-demand and/or regular prophylactic infusions of factor replacement therapy to control or prevent the risk of bleeding.[1,3]

**About Takeda Hematology**
Takeda is a leader in hemophilia with the longest heritage and a market-leading portfolio, backed by established safety and efficacy profiles with decades of real-world experience. We have 70+ years of experience driving innovation for patients and a broad portfolio of 11 products across multiple bleeding disorders. Our experience as leaders in hematology means we are well prepared to meet today's needs as we pursue future developments in the treatment of bleeding disorders. Together with the hematology community, we are committed to raising expectations for the future, including earlier diagnosis, individualized bleed protection, and more personalized patient care.

**About Takeda Pharmaceutical Company Limited**
Takeda Pharmaceutical Company Limited (TSE:4502/NYSE:TAK) is a global, values-based, R&D-driven biopharmaceutical leader headquartered in Japan, committed to bringing Better Health and a Brighter Future to patients by translating science into highly-innovative medicines. Takeda focuses its R&D efforts on four therapeutic areas: Oncology, Rare Diseases, Neuroscience, and Gastroenterology (GI). We also make targeted R&D investments in Plasma-Derived Therapies and Vaccines. We are focusing on developing highly innovative medicines that contribute to making a difference in people's lives by advancing the frontier of new treatment options and leveraging our enhanced collaborative R&D engine and capabilities to create a robust, modality-diverse pipeline. Our employees are committed to improving quality of life for patients and to working with our partners in health care in approximately 80 countries.