Canadian Hemophilia Society
Help Stop the Bleeding

UPDATE ON CBS CONTRACTS FOR FVIII AND FIX FOR 2018-2020

MONTREAL – December 15, 2017 – On October 31, Canadian Blood Services (CBS) released the results of the Request for Proposals (RFP) for the period of April 1, 2018 to March 31, 2020 with the potential of two one-year extensions. As communicated by the Canadian Hemophilia Society (CHS) at the time, those results were dependent on several decisions by Health Canada. Health Canada's decisions are now known and they have an impact on the product mix first announced by CBS.

ADYNOVATE (rFVIII from Shire) currently does not have an indication (approval for specific use) for children with hemophilia A under 12 years of age. Similarly, REBINYN (rFIX from Novo Nordisk) is not indicated for routine prophylaxis in children and adolescents with hemophilia B under 18 years of age; however, REBINYN can be prescribed to treat bleeding and for short-term prevention of bleeding in all age groups. Similar decisions were made by the European Medicines Agency. Both ADYNOVATE and REBINYN use PEG (polyethylene glycol) to extend the half-lives of the FVIII and IX molecules. It is not known if and when Health Canada will grant indications for prophylaxis use of these products in the age groups mentioned above. As a result, two extended half-life products from Bioverativ—ELOCTATE (rFVIII) and ALPROLIX (rFIX)—will continue to be available for these age groups.

Regardless of future Health Canada decisions, Eloctate will remain accessible for minimally treated patients (up to 100 exposure days) and for patients currently on an immune tolerance protocols. An "exposure day" is defined as a day during which FVIII was infused. Please see below for more details on all the products that will be made available through CBS.

Hemophilia A

The three standard half-life recombinant factor VIII products currently available—KOVALTRY (Bayer), NUWIQ (Octapharma) and XYNTHA (Pfizer) will continue to be available. ADYNOVATE (Shire), a pegylated form of ADVATE with slightly extended half-life over standard products, will be added to the portfolio.

ELOCTATE (Bioverativ) will be available on a named-patient basis for previously untreated patients currently using ELOCTATE up to a maximum of 100 exposure days for the duration of the contract. Pediatric and adult patients currently receiving ELOCTATE for immune tolerance induction (ITI) to eliminate an inhibitor will be able to continue using ELOCTATE to the end of their ITI protocols, again on a named-patient basis. For the foreseeable future, children aged 12 years and under will continue to have access to ELOCTATE.

Hemophilia B

The standard half-life recombinant factor IX product, BENEFIX (Pfizer), will continue to be available. REBINYN (Novo Nordisk), a pegylated FIX with an extended half-life five times longer than standard products, will be added to the portfolio. For the foreseeable

future, children and adolescents aged 18 years and under will continue to have access to ALPROLIX (Bioverativ) for routine prophylaxis.

Transition

Exact details of the timing of transition for those patients changing products have not yet been worked out. Switches could take place before or after April 1, 2018. Questions about possible switching to a different product should be directed to hemophilia treatment centres.

RFP process

The RFP process was a rigorous one that took place over five months. The Selection Advisory Committee included two advisors from the CHS, two from the Association of Hemophilia Clinic Directors of Canada and one from the Canadian Association of Nurses in Hemophilia Care. Their involvement allowed patient needs and medical expertise to be heard in the Committee making recommendations to CBS.

The cost reduction as a result of these RFPs, considering all plasma protein and recombinant products, is estimated by CBS at $125 million in 2018-19 and $190 million in 2019-2020. A significant percentage of these savings can be attributed to factor concentrates. The CHS will make every effort to have at least a portion of these savings re-invested in care, including funding of the Canadian Bleeding Disorders Registry.

See (**https://www.blood.ca/en/hospitals/customer-letters**) for two documents prepared by CBS on the RFP results: *Frequently Asked Questions* and *Plasma Protein Products Transition*.

Note that the Héma-Québec RFP process for the supply of recombinant factor VIII for the period 2018-2020 is currently underway. The awarding of contracts will be announced early in the new year.

The March issue of *Hemophilia Today* will focus on the two new products in the factor concentrate portfolio, ADYNOVATE and REBINYN.

About the Canadian Hemophilia Society

Founded in 1953, the Canadian Hemophilia Society is a national voluntary health charity. Its mission is to improve the health and quality of life of all people in Canada with inherited bleeding disorders and ultimately to find cures. Its vision is a world free from the pain and suffering of inherited bleeding disorders.

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