Working to Improve Hemophilia A Testing:
Precision BioLogic presents new data at the 64th Annual SSC meeting

For Immediate Release
HALIFAX, July 19, 2018—Precision BioLogic today unveiled data from a study using a new kit for a Modified Nijmegen-Bethesda Assay (MNBA) at the International Society on Thrombosis and Haemostasis’ Scientific and Standardization Committee (SSC) meeting in Dublin. Recognizing the need to standardize and improve Factor VIII (FVIII) inhibitor testing for people with hemophilia A, the company developed the new MNBA kit and the recent study in collaboration with Roche and Genentech, a member of the Roche Group.

Data presented builds on findings released at the Thrombosis & Hemostasis Societies of North America (THSNA) 2018 Summit in San Diego, California and the World Federation of Hemophilia (WFH) 2018 World Congress in Glasgow, Scotland. The latest data demonstrate that a bovine-based chromogenic MNBA is suitable for FVIII inhibitor measurement in plasma samples containing HEMLIBRA® (emicizumab-kxwh), a bispecific antibody that is approved by the U.S. Food and Drug Administration (FDA) and European Commission for the prophylactic treatment of hemophilia A with factor VIII inhibitors.

“We’re seeing promising advancements in the treatment of bleeding disorders,” says Paul Empey, President & CEO of Precision BioLogic. “We are hopeful that combining accurate diagnosis and monitoring with potential advancements could improve the quality of life for people with bleeding disorders. Precision BioLogic is proud to be at the forefront of this promising research.”

A poster of the latest study, Emicizumab Impact on Factor VIII Inhibitor Determination in Plasma Samples from Persons with Hemophilia A (PwHA) Using a New Kit for Modified Nijmegen-Bethesda Assay (MNBA), as well as previous studies, can be downloaded from the publications page of the Precision BioLogic website.

Precision BioLogic’s newly developed MNBA kit was used in the study. To eliminate FVIII depleted plasma as a potential source of variant and standardize inhibitor titer measurement, the kit was developed with the following components:

- Imidazole-buffered pooled normal plasma
- Imidazole-buffered bovine serum albumin
- Positive FVIII inhibitor control
- FVIII inhibitor-free human plasma

All kit components are frozen, like Precision BioLogic’s line of cryocheck™ diagnostic products, which closely resemble frozen patient samples.
Precision BioLogic plans to commercialize the kit and will seek clearance from regulatory authorities around the globe beginning in late 2018. The company is actively pursuing other opportunities to innovate in the field of hemostasis and diagnostics.

**About Hemophilia A and Inhibitors**

Hemophilia A is an inherited bleeding disorder caused by insufficient clotting factor VIII (FVIII) in the blood. People with hemophilia A experience prolonged bleeding, which can lead to permanent joint damage and life-threatening hemorrhages. The standard treatment for people with hemophilia A without inhibitors is intravenous (IV) FVIII replacement therapy with recombinant FVIII (rFVIII) or plasma-derived FVIII (pdFVIII) concentrates. Prophylaxis, the regular infusion of clotting factor concentrates, is used to prevent bleeds thereby minimizing joint damage.

Unfortunately, up to 30% of people with hemophilia A develop inhibitors, an immune response to treatment with clotting factor concentrates. Inhibitors make it more difficult to manage and treat hemophilia. In fact, according to the World Federation of Hemophilia, apart from access to care and treatment, inhibitors are the most serious challenge in hemophilia care today. While routine blood tests may suggest the presence of anti-factor FVIII antibodies, specialized testing is important to confirm not only the presence of inhibitors but also the quantitation to effectively adjust treatment. Current methods for inhibitor testing vary from lab to lab and there is not an FDA-cleared gold standard for reference.

**About Precision BioLogic**

Precision BioLogic is a privately-held company that develops, manufactures and markets specialized products used by medical professionals and researchers around the globe to diagnose coagulation disorders. Precision BioLogic also has several active initiatives with pharmaceutical partners who seek to ensure that the diagnostic implications for their novel therapeutic agents have been well characterized. For more information, visit [www.precisionbiologic.com](http://www.precisionbiologic.com).

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