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Bayer invest 500 million Euros to expand its capacity

19 March 2014 | News | By BioSpectrum Bureau

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The investigational therapy options for hemophilia patients - a plasma protein-free rFVIII (BAY 81-8973) and a long-acting rFVIII (BAY 94-9027) - are both currently in Phase III clinical trials.

In February 2014, Bayer HealthCare announced positive results from the PROTECT VIII trial evaluating Bayer's site-specific PEGylated rFVIII (BAY 94-9027).

"This investment will be one of the largest in the history of Bayer HealthCare and reflects our strong commitment in the field of hemophilia A," said Dr Olivier Brandicourt, ceo, Bayer HealthCare.

Bayer's approved hemophilia A therapy product Kogenate FS/Kogenate Bayer is manufactured exclusively in Berkeley, California, USA.

Establishing an additional supply source in Germany will help the company to prepare for production of the anticipated new therapy options and address the growing demand in this therapeutic area.

Subject to the results of the ongoing clinical trials, Bayer is planning to file BAY 81-8973 for approval with the regulatory authorities in the second half of 2014 with first launches planned in Q4/2015.

Furthermore, a site-specific PEGylated rFVIII product currently being investigated may result in a significant benefit for long-term outcomes and quality of life improvements for people with hemophilia A.

Today, prophylactic treatment for hemophilia patients makes it necessary that patients infuse themselves two to three times a week.

The investigational product BAY 94-9027 is a long-acting factor VIII that is being studied in patients in a once-weekly

prophylactic dosing regimen.

Bayer HealthCare recently announced positive results with the site-specific PEGylated rFVIII product demonstrating protection from bleeds comparable to current prophylactic dose regimens with infusion intervals of up to seven days.

Bayer is planning to file BAY 94-9027 for approval with the regulatory authorities in the second half of 2015.