BIOSIMILARS HAVE THE POTENTIAL TO EXPAND ACCESS FOR PATIENTS.

IQVIA (2018). The Impact of Biosimilar Competition in Europe. PDF file. Retrieved from:https://www.medicinesforeurope.com/wp-content/uploads/2017/05/IMS-Biosimilar-2017_V9.pdf

ABP 938

ABP 938 is being developed as a 'biosimilar' to Eylea® (also known as aflibercept)

ADDITIONAL RESOURCES

www.amgenbiosimilars.com

www.fda.gov/drugs/biosimilars/biosimilars-basics-patients

www.ema.europa.eu/en/human-regulatory/overview/biosimilar-medicines-overview

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BIOSIMILAR MEDICINES

Information for the Patient

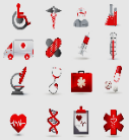
A STUDY EVALUATING ABP 938 COMPARED WITH AFLIBERCEPT IN ADULTS with Neovascular Age-related Macular Degeneration

Sponsor: Amgen Inc.

Protocol No: 20170542

THE DEVELOPMENT OF BIOSIMILARS

ABP 938 is being developed as a 'biosimilar' to Eylea® or aflibercept for the treatment of adults with Neovascular (wet) Age-Related Macular Degeneration (AMD). Aflibercept is part of a class of medications called biologic medicines.



WHAT IS A BIOLOGIC MEDICINE?

Medications such as aflibercept are proteins and are known as biologic medicines. Biologic medicines are much different than common medicines (non-biologic), such as aspirin. A common medicine is typically made through a chemical process, which means that it is made by combining specific chemicals together to make a medicine. A biologic medicine is made in a living system such as an animal cell, microorganism, or plant. Biologic medicines components are much larger, often up to 1,000 times the size of common medicines and are very complex to make.

WHAT IS A BIOSIMILAR?

A biosimilar is a biologic medicine highly similar to another biologic medicine already approved for use by regulatory agencies, such as the European Medicines Agency (EMA) or the Food and Drug Administration (FDA) called 'reference medicine'. ABP 938 is considered a biosimilar candidate to the reference medicine aflibercept.

Highly similar means that the biosimilar and its reference medicine are essentially the same, though there may be minor differences in their active substances. These minor differences are due to the fact that these active substances are usually large and complex medicines and that they are made by living cells.

Biosimilars are approved for use by regulatory agencies based on a thorough comparison to the reference medicine. The thorough comparison includes studying the biosimilar medicine candidate (ABP 938) against the reference medicine (aflibercept) in clinical studies, such as this study.

IS A BIOSIMILAR A GENERIC MEDICINE?

No, a generic medicine is an exact copy of the original medicine and is expected to work the same way as the original product. Since biosimilars are large complex proteins made in living cells, an exact copy of the reference medicine cannot be made. However, when approved, a biosimilar is considered highly similar to the reference medicine in terms of structure, activity, effectiveness, and its safety.

HOW IS A BIOSIMILAR MEDICATION DEVELOPED?

Regulatory authorities apply strict criteria in their evaluation of biosimilar medicines for approval. The main part of the evaluation is a comparison of the biosimilar medicine with its reference medicine to show that there are no meaningful differences between them. These studies compare the quality (methods and controls used to make the medicine), effectiveness, and safety. The studies on quality include a wide range of comparisons of the structure and biological activity of the biosimilar's active substances. The studies, including this study, on effectiveness and safety should show that there are no meaningful differences in the benefits and risks (effectiveness and safety).

WHAT IS THIS STUDY TRYING TO ACHIEVE?

The purpose of this study is to confirm that there are no meaningful differences in the benefits and risks (effectiveness and safety) between ABP 938 and aflibercept in patients with Neovascular Age-Related Macular Degeneration. This study will complete the studies required for regulatory authorities to evaluate that ABP 938 is approved as a biosimilar to aflibercept.

WHAT IS THE BENEFIT TO ME IN PARTICIPATING IN THIS STUDY?

There is no guarantee that you will benefit from study participation. Your health and any changes in your health will be closely monitored throughout the study. The treatment you receive in this study may result in an improvement of AMD or you may have no improvement at all. It is through this type of research that improved treatments for AMD may develop. The potential success of this study may result in ABP 938's approval as a biosimilar to aflibercept.