Biosimilars – What are they?

What are biologics and biosimilars?
Biologics are medicines made from living cells, manufactured in living systems. The manufacturing process is complex with extensive quality controls, because the living systems used to produce biologics can change ever so slightly over time. A biosimilar of a biologic is similar to a generic version of a conventional drug, but there is a key difference. By law, a generic must be an exact copy of the original medication, or reference product. Because of the complexity of the biological medication, it is not possible to exactly replicate biologic reference products. Therefore, biosimilars must be highly similar in terms of structure and function and lack clinically meaningful difference in terms of safety and efficacy to their reference product.

What are some examples of biosimilars?
Only six biosimilars are commercially available in the U.S. as of October 2018. These include Zarxio®, Nivestym™, and Fulphila™, which treat neutropenia; Inflectra® and Renflexis®, which treat inflammatory diseases; and Retacrit™, which treats anemia. Six additional products — treatments for various cancers, as well as additional treatments for inflammatory diseases — have been approved by the FDA but are not yet commercially available.

Are biosimilars approved for all the same indications as the reference product?
Biosimilars may be approved for all or some of the indications as the reference product. Some biosimilars may have a subset of indications as the reference product due to patent exclusivity of certain indications. There is no clinical reason why the biosimilar cannot be used for all indications of the reference product, even though the biosimilar might not share the same indications.

What are the potential benefits of biosimilars?
As patents start to expire on the biologic drugs, the rise of biosimilars brings increased competition to the market resulting in potentially lower treatment cost. We also expect to see innovation evolve with product competition. Examples of differentiating product attributes already seen include individualized anti-drug antibody monitoring and subcutaneous formulations for greater convenience.

Will the pharmacist substitute a reference product with the biosimilar if the prescription indicates may substitute?
Although the biosimilar lacks clinically meaningful difference compared to its reference product, it is not automatically substitutable by the pharmacist, unless it is rated as interchangeable. To date, no biosimilars are considered interchangeable. The prescription needs to be written for the biosimilar by name.