Elanco Announces Strategic Shift in Dairy Portfolio Focus

Optimizing investment to focus on future innovation; exploring strategic options for rbST and Augusta, Georgia manufacturing facility

GREENFIELD, IND. Sept. 29, 2017 – Elanco Animal Health, a division of Eli Lilly and Company (NYSE: LLY), announced today a strategic shift in its dairy portfolio. The company will optimize investment to focus on future dairy innovations that address the most challenging issues and diseases farmers face in their herds today. Concurrently, Elanco is exploring strategic options for rbST, including seeking a buyer for the molecule and its Augusta, Ga., manufacturing facility.

The decision will allow the company to bring new products that help farmers protect animal health, enhance animal care, and improve profitability.

“There are still many unmet needs dairy farmers face today and we are focused on optimizing our investment on new dairy innovation to fill the gaps we see,” said Jeff Simmons, president of Elanco. “rbST is an important innovation for dairy farmers around the world, bringing substantial benefits to dairy farmers, consumers, and the environment for nearly 25 years. As we move forward, we are seeking to shift to new areas of innovation to bring greater future value to the industry.”

Innovation Focus

Animal health is dynamic, and nowhere is that more apparent than in the dairy, where lactating cows face numerous physiological and metabolic changes that can interfere with energy balance and immune function.

“As we look to the future, we’re exploring innovative solutions that work with the animal’s own immune system and other biological mechanisms to help her be more resistant and resilient to stress, disease and other challenges,” said Aaron Schacht, vice president Research and Development at Elanco.

Elanco is committed to continuing research in this space to provide dairy farmers a mix of preventatives and treatments to address unmet needs:

- **Bovine Respiratory Disease (BRD):** Bovine respiratory disease is a complex disease that causes respiratory distress and reproductive failure in cattle. Despite the widespread use of vaccines, U.S. surveys have estimated that anywhere from 12-16
percent of pre-weaned dairy heifer calves are affected with BRD\(^1\), and the disease is estimated to cost the North American cattle industry more than $500 million annually.\(^2\)

- **Mycoplasma**: This highly infectious disease causes respiratory infection in calves and mastitis in cows, and can be difficult to treat\(^3\). Over the past decade, the incidence rates of Mycoplasma have been steadily increasing, from 8 percent of dairies testing positive in 2002\(^4\) to 7-20 percent of bulk tanks testing positive in 2011 studies.\(^5\) Mastitis affects 20-25 percent of dairy herds and costs more than $200 million in direct costs from treatment and discarded milk annually in the United States alone.\(^6\)

- **Mycobacterium**: Currently there is no treatment for cattle with Mycobacterium, which can lead to two major diseases: Johne’s\(^7\), a chronic infection that impacts a cow’s immune function, and TB\(^8\), which can cost dairy producers cattle through required culling.

- **Digestive Health**: Early disease prevention with non-medicated feed additives, such as enzymes, prebiotics and probiotics, can improve microbiome health, helping protect from disease even before clinical signs develop thus lessening the need for antibiotics. Elanco is currently exploring antibiotic alternatives and feed ingredients that will improve the digestive health of ruminants.

“We will also continue to study Imrestor\(^8\) (pegbovigrastim injection), as we evaluate where its mechanism shows potential to address other key challenges the dairy cow faces,” Schacht said.

Imrestor is approved in the United States to reduce the incidence of clinical mastitis in the first 30 days of lactation in periparturient dairy cows and periparturient replacement dairy heifers.

**About Elanco**

Elanco provides comprehensive products and knowledge services to improve animal health and food-animal production in more than 70 countries around the world. We value innovation, both in scientific research and daily operations, and strive to cultivate a collaborative work environment for more than 6,500 employees worldwide. Together with our customers, we are committed to raising awareness about global food security, and celebrating and supporting the human-animal bond. Founded in 1954, Elanco is a division of Eli Lilly and Company. Our worldwide headquarters and research facilities are located in Greenfield, Indiana. Visit us at Elanco.com and EnoughMovement.com.

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\(^1\)Guterbock, Walter. (2014). The impact of BRD: The current dairy experience. Animal health research reviews / Conference of Research Workers in Animal Diseases. 15. 1-5\(^2\)

\(^2\)https://ncbi.nlm.nih.gov/pubmed/20003641

\(^3\)https://www.addl.purdue.edu/newsletters/2004/fall/mycoplasma.htm


\(^6\)Cady, Elanco. 2016. Data on File


\(^8\)https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2710499/
**Important Safety Information Regarding Imrestor**

Not for use in humans. Keep out of reach of children. In case of accidental self-injection, wash the site of injection thoroughly with clean running water. Foreign proteins such as pegbovigrastim have the potential to cause anaphylactic-type reactions. No withdrawal period or milk discard time is required when used according to the labeling. Do not use Imrestor to treat cows with clinical mastitis because effectiveness has not been demonstrated for this use. Some cases of hypersensitivity-type reactions have been observed in studies outside the United States within five minutes to two hours, occurring most often after the first administration of Imrestor. Clinical signs may include elevated respiratory rate, dyspnea, urticaria, sweating, dependent edema, swollen mucous membranes, and/or hypersalivation, and, rarely, death. These reactions resolve within hours of onset with or without therapeutic intervention and have not been shown to reoccur with subsequent injections of Imrestor. Abomasal ulcerations/erosions were observed in the Margin of Safety studies; it was concluded that these findings were not clinically relevant. For product label, including complete safety and use information, [click here](#).

This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about the Elanco’s dairy portfolio, product pipeline, changes to its strategic focus on rbST and changes to the Augusta, Georgia manufacturing site, and reflects Elanco’s current beliefs. Actual results may differ materially due to various factors. As with any such undertaking, there are substantial risks and uncertainties in the processes of product research and development and commercialization. Among other things, there can be no guarantees that the company will be realize the anticipated benefits of the strategic portfolio shift or any potential strategic changes relating to rbST and the Augusta, Georgia site; that the dairy portfolio will be commercially successful; or that Elanco’s dairy pipeline will yield commercially successful products. For further discussion of these and other risks and uncertainties, please see Lilly’s latest Forms 10-Q and 10-K filed with the U.S. Securities and Exchange Commission. Except as required by law, Elanco undertakes no duty to update forward-looking statements.

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