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## ORGANIC AND INORGANIC CHEMISTRY

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**Process development towards a green manufacturing route for *letermovir* exploiting novel asymmetric reactions****Yingju Xu**

Merck and Co., Inc., USA

Merck aims to develop the best chemistry at time of regulatory filing, with the ultimate goal of the zero waste API manufacturing process. Achieving this ambitious goal is enabled by an innovative, green by design, development strategy, to progress from initial route design through to a fully optimized sustainable commercial manufacturing process. *Letermovir* is an antiviral drug currently in late-stage development for the treatment of cytomegalovirus infections. This presentation will describe key aspects of the synthesis development that led to an efficient, robust and green manufacturing process. A chemically stable and fully recyclable organo catalyst has been discovered to promote this novel asymmetric aza-Michael cyclization. The remainder of the synthesis has been fully optimized to reduce catalyst loading, minimize the number and amount of solvents, employ telescoped processing where possible, and to maximize atom-economy. Implementation, demonstration and validation of the new process were successfully completed in 2016. Compared to the benchmark process used for the generation of the initial phase III clinical supplies, this revolutionary new synthesis reduces PMI by 73%, increases the overall yield by more than 60%, and reduces raw material costs by 93%. Life-cycle assessment reveals that the new process reduces carbon footprint and water usage by 89% and 90%, respectively.

**Biography**

Yingju Xu has attended Nanjing University, China, receiving her BA and MS in Organic Chemistry. She then conducted Graduate Research in the laboratory of Professor Soctt J Miller at Boston College, MA, earning her PhD in 2007. She joined the Department of Process Chemistry at Merck in 2007. She has 10 years of process development experience on various drug candidates. Her research experience at Merck focuses on discovery of innovative approaches to access drug candidate via low-cost and sustainable processes, design and development of robust green manufacturing processes for target drug candidates, as well as late stage process development to support filing and commercialization.

yingju\_xu@merck.com

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