DEVICE RECALL UPDATE Notice 3 of 3

December 22, 2017

Species Update - Synvisc-One Voluntary Recall Lot 7RSL021

Dear Health Care Provider,

I am writing to further inform you regarding the Sanofi Genzyme initiated voluntary product recall for **one (1) lot of Synvisc-One®** (hylan G-F 20) **lot 7RSL021** on December 11, 2017, due to an ongoing investigation which revealed the presence of microbial, *Methylobacterium thiocyanatum*, an alpha proteobacterial class, aerobic, Gram negative rod. The microbe is a common airborne organism and is a rare cause of human infections. This species can cause infection in both immunocompromised and immunocompetent patients.

Sensitivity analysis of the Methylobacterium thiocyanatum species from **Synvisc-One®** (hylan G-F 20) **lot 7RSL021** demonstrated that it is susceptible to Piperacillin, Cefepime, Imipenem, Gentamicin, Tobramycin and Ciprofloxacin, and is resistant to Ceftazidine, Azteonam, Meropenem, Colistin and Polymyxin B. Consistent with the information suggested in available literature, the organism grows fastidiously on ordinary media. Growth of this organism may be seen at day seven on TSA or at day 14 in liquid media. Optimum growth may be seen on R2A agar at 30-35°C & pH 7.2 +/- .2 at days 2-4.

No other Synvisc-One® or SYNVISC® lots are impacted. This voluntary product recall is isolated to one product lot within the US only and is at the physician, hospital and wholesale/pharmacy level.

This recalled lot was distributed in the US between October 25, 2017 and November 7, 2017. Sanofi Genzyme is working with its distributors to ensure that all products in the specified lot are returned to the company.

If you currently have product from the impacted Synvisc-One® lot **7RSL021** and have not received a recall letter from GENCO, please contact them at 855-838-5782 (Monday-Friday 7am-5pm CST) to obtain a return kit.

If you have any medical or clinical questions about the voluntary product recall please call Sanofi Medical Information Services at 1-800-633-1610 option 1.

Patient inquiries regarding this voluntary recall should be directed to Sanofi U.S. Customer Service at 1-800-633-1610 option 7 then 4.This voluntary recall has been initiated with the knowledge of the US Food and Drug Administration.

The most frequently reported adverse events associated with the voluntarily recalled lot are listed within the product labeling. All patients who experience symptoms should be managed based on standard of care whether or not they have reported an adverse event related to this voluntarily recalled lot. Any adverse event related to the use of Synvisc-One® should be reported to:

- Sanofi U.S. LLC at 1-800-633-1610 option 2 or
- FDA at 1-800-FDA-1088 or http://www.fda.gov/medwatch.

Sincerely,

William Daley, MD, MPH
VP Medical Affairs/Biosurgery - Synvisc