Grifols – Withdrawal of Gamunex-C® (immune globulin [human])

- On November 5, 2019, Grifols Therapeutics announced a voluntary, consumer-level withdrawal of one lot of Gamunex-C (immune globulin [human]) injection due to a higher rate of allergic/hypersensitivity type reactions, a small number of which were considered medically significant.

- The withdrawn Gamunex-C injection was distributed in the U.S. and had a market release date of June 20, 2019.

Product Description	NDC#	Lot# (Expiration Date)
Gamunex-C 10%	13533-800-24	A1GLD00622 (5/18/2022)

- Gamunex-C is indicated for the treatment of primary humoral immunodeficiency in patients two years of age and older; idiopathic thrombocytopenic purpura in adults and children; and chronic inflammatory demyelinating polyneuropathy in adults.

- Per Grifols, hypersensitivity and anaphylactic/anaphylactoid reactions are a known risk with IVIG products.

- Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to using the withdrawn Gamunex-C injection.

- Anyone with an existing inventory of the withdrawn product should stop use and quarantine the product immediately.

- For more information regarding this withdrawal, contact Grifols US Clinical Communications at **1-800-520-2807** for further information regarding this withdrawal.