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

- On June 28, 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- The withdrawn Gamunex-C injection was distributed in the U.S. and had a market release date of May 21, 2019:

Product Description	NDC#	Lot# (Expiration Date)
Gamunex-C 10% 20 gm/200 mL	13533-800-24	A4GLD00502 (4/6/2022)

- 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contact their healthcare provider for further guidance and potential change of treatment before they stop taking the withdrawn product.

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should contact their healthcare provider if they have experienced any problems that may be related to using the withdrawn Gamunex-C injection.

- Pharmacies and healthcare facilities that have the withdrawn drug product should immediately quarantine and stop dispensing the withdrawn drug product.

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