Statement#3: There are approximately 100+ biologic drugs[1,2] in clinical trials that are expected to be launched in a prefilled syringe device across Europe. Many of these prefilled syringes will potentially be with PFAS coated stoppers due to the sensitivity of these new biologics.

Source/Reference:

1. Biologic injectable drugs are defined in GlobalData* 2023 (downloaded on May 5th, 2023) filtered according to highest development stage (Discovery; Preclinical; Phase III; Phase II; Phase I; IND/CTA filed; Discontinued; Inactive), drug geography: Europe, route of administration (subcutaneous OR intramuscular OR intravenous injection), and molecule type: biologic (including oligonucleotide)

*Based on our understanding on GlobalData's (https://www.globaldata.com/) data acquisition methodology for the data referenced in this document, GlobalData sources data from public sources only and consolidates the information in a presentable format. Examples of such sources may include pharmaceutical company public presentations, online platforms such as https://clinicaltrials.gov/ , https://euclinicaltrials.eu/ etc.

2. Biologic injectable drugs are defined in IQVIA** (https://www.iqvia.com/) Smart MIDAS 2022 report (downloaded on May 15th, 2023) according to the nature of the drug (eg. biologics/large molecules), type of container (eg. prefilled syringe, autoinjector etc), therapeutic indication (ATC), and region.

**Based on our understanding on IQVIA's data acquisition methodology for the data referenced in this document, IQVIA tracks data at multiple points of the pharmaceutical distribution system. IQVIA acquires data based on the pharmaceutical drug reported at the final point of use (for eg. pharmacy, hospitals). Data is also acquired via entities such as distributors, wholesalers, and pharmaceutical companies who sell products directly to hospitals, pharmacies, clinics etc. IQVIA seems to diligently align with international data protection practices as referenced in the following link: https://www.iqvia.com/about-us/privacy/gdpr-at-iqvia

Substantiation:

Global Data database download is relative to the following segmentation:

Definition: Nature of the drug (biologics/large molecules), route of administration (intravenous, subcutaneous, intramuscular), and frequency of treatment

Calculation:

A) Based on IQVIA Midas report:[2]
Number of marketed biologic drugs sold in prefilled syringes and autoinjectors in Europe in 2022 = 304

Number of marketed biologic drugs sold in different containers (eg. prefilled syringes, autoinjectors, vials, ampoules, cartridges etc.) in Europe in 2022 = 1190

Percentage of the number of marketed biologic drugs sold in prefilled syringes in Europe (relative to different containers)
= 304/1190 = 25%

B) Estimated number of biologic drugs[1] in clinical trials in Europe = 492

C) Estimated number of biologic drugs[1] in clinical trials in Europe expected to be launched in a prefilled syringe with PFAs stopper = 25% X Estimated number of biologic drugs[1] in clinical trials in Europe

= 25% X 492 = 123