EXHIBIT 1

Declaration of John Geissler
December 6, 2019

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
ASHEVILLE DIVISION

EXELA PHARMA SCIENCES, LLC, Plaintiff, vs. SANDOZ, INC., Defendant.	Civil Action No. 1:19-CV-318 **DECLARATION OF JOHN GEISSLER**

I, JOHN GEISSLER, being duly sworn, depose and state as follows:

1. My name is John Geissler. I am over 21 years of age and competent to testify to the statement set forth in this declaration.

2. The facts set forth in this declaration are based on my personal knowledge and upon information available to me through the files and records of Sandoz Inc. (Sandoz). If called upon as a witness, I could and would testify to those facts.

3. Since November 2018, I have served as the Global Head, GxP Audit and CAR-T Compliance at Novartis. Before that, I was the Global Head, Compliance, Incident Management and Audit at Novartis since July 2016. My responsibilities during this time period have included current Good Manufacturing Practice (GMP) compliance, pharmacovigilance, and overseeing the supplier audit programs across all Novartis Technical Operations. From February 2014 to July 2016, I served as the Global Head, Compliance and Audit at Sandoz, a division of Novartis. I started my employment with Novartis in August 2012 as the Executive Director and Head, GMP Compliance, until February 2014. I have held positions relating to manufacturing and product quality and good compliance practices (GxP) at Sandoz and other pharmaceutical companies since 1999. I earned a B.S. in Chemistry from Rutgers University in 1989.

4. Until 2016, Allergy Laboratories, Inc. (Allergy Labs) was the contract manufacturer that Sandoz used to produce L-Cysteine Hydrochloride Injection, USP, 50 mg/mL (L-Cysteine). Based on documents in our files that I have reviewed, Allergy Labs manufactured this L-Cysteine product at least as far back as 2008. At that time, Allergy Labs contract manufactured this product for Parenta Pharmaceuticals (an EBEWE company). Attached as **Exhibit A** is a true and correct copy of Parenta Pharmaceuticals 2008 Annual Product Review (APR) for L-Cysteine Hydrochloride Injection, USP (50 mg/mL). This document, dated June 19, 2009, states that EBEWE Parenta Pharmaceuticals was the owner of the product, and Allergy Labs was its manufacturer. The attachment to this document states that the aluminum content was within the specification, under 5000 ppb, and that all batch records reviewed for the relevant time period contained passing aluminum content results, based on this specification. In 2009, Sandoz acquired EBEWE. *See* https://www.pharmaceuticalonline.com/doc/sandoz-completes-acquisition-of-ebewe-pharma-0001. It is my understanding that Sandoz acquired the L-Cysteine product as part of this acquisition and continued to engage Allergy Labs as the contract manufacturer for this product until 2016.

5. In late 2014, following an FDA manufacturing inspection, Allergy Labs suspended production of L-Cysteine at its Oklahoma City, OK facility based on inspectional observations. At this time, Sandoz placed its L-Cysteine inventory on distribution hold pending a risk assessment. In or around January 2015, FDA approached Sandoz to explore options for increasing the supply of L-Cysteine. To address the shortage of L-Cysteine in the U.S market, Sandoz developed and implemented an "as-is" technology transfer (tech transfer) of the manufacturing process from Allergy Labs to the Sandoz site in Boucherville, Canada (BV). I played a major role in developing the strategy for the "as-is" tech transfer.

6. The BV site in Canada is, and has been since at least 2015, an FDA-registered manufacturing facility under Section 510 of the Federal Food, Drug and Cosmetic Act (21 USC 360) and 21 CFR Part 207. The BV site is currently registered under "Services Pharmaceutiques Avara Boucherville Inc.," which is currently owned by Sandoz. The registration can be verified at FDA's Drug Establishments Current Registration Site, *available at*: https://www.accessdata.fda.gov/scripts/cder/drls/getdrls.cfm. Attached as **Exhibit B** is a true and correct copy of the data from FDA's website demonstrating that Services Pharmaceutiques Avara Boucherville Inc. is an FDA-registered manufacturing facility. The BV site has been involved in sterile drug manufacturing since at least 1997. The facility and sterile filling line manufacturing equipment used to manufacture the L-Cysteine product have been in operations since 2008.

7. In June 2015, a cross-functional team, including manufacturing quality experts, finalized a written protocol to evaluate the process and specifications for transfer to the BV site. The "as-is" transfer to the BV site maintained the formulation, product specifications, and manufacturing technologies used to manufacture the product at Allergy Labs. The transfer also provided for the same Active Pharmaceutical Ingredient (API) supplier, an equivalent process for formulation and filling 10 mL vials, and equivalent primary packaging and labeling. The tech transfer protocol also evaluated the product's critical quality attributes and found that the BV site's response and control strategies were adequate. The product specifications for release of L-Cysteine finished product, including the test method and limits for aluminum content (not more than 5000 ppb) were not changed during the tech transfer to the BV site.

8. In addition, the labeling of both products manufactured by Allergy Labs and the BV site refer to the same maximum aluminum content level. The statement on the immediate

container labels that the product "Contains no more than 5,000 mcg/L of aluminum" was not changed. No changes were made to the labeling, other than manufacturer-related changes, such as manufacturer name and NDC numbers. The labeling complies with FDA regulation, 21 CFR 201.323, which requires the maximum level of aluminum present at expiry to be stated on the immediate container label of all small volume parenteral (SVP) drug products used in total parenteral nutrition. An SVP is defined as a parenteral product that contains less than 100 mL. *See, e.g.*, https://www.fda.gov/media/108408/download. Because L-Cysteine is supplied in 10 mL vials, it is considered an SVP. The labeling also maintains without change the aluminum warning statement required by 21 CFR 201.323(e).

9. On January 21, 2016, Sandoz submitted a letter to FDA requesting the agency's agreement in writing to allow importation of L-Cysteine from the BV site in Canada. The letter to FDA included information and records requested by FDA's Office of Drug Shortage, including the tests and specifications for L-Cysteine product. A true and correct copy of a document titled "Inspection Plan" provided as an attachment to the letter to FDA is attached as **Exhibit C**. The Inspection Plan references the test methods and established specifications for the product during batch release testing, including aluminum content levels, which remained unchanged after the tech transfer from Allergy Labs to the BV site.

10. The BV site has maintained adequately controlled manufacturing operations and a high level of compliance with FDA's Current Good Manufacturing Practice (cGMP) requirements. In August 2016 and June 2018, FDA investigators performed cGMP inspections of the BV site. FDA investigators evaluated the facilities and equipment, packaging and labeling, production system, and quality system at the BV site. FDA did not issue a Form 483 for any inspectional observations following either site inspection. FDA classified both

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