Congress of the United States

Washington, DC 20510

October 20, 2016

Paris Panayiotopoulos
President and Chief Executive Officer
ARIAD Pharmaceuticals, Inc.
26 Landsdowne Street
Cambridge, MA 02139

Dear Mr. Panayiotopoulos:

We are writing today to request information about ARIAD Pharmaceuticals, Inc.'s (ARIAD) repeated and staggering price increases for the drug Iclusig (ponatinib). Reports indicate Iclusig has undergone multiple price increases over the last four years – including four price increases this year alone – adding more than $80,000 to the drug's already high annual price tag.

Iclusig is used to treat chronic myeloid leukemia (CML), a type of bone marrow cancer in which the marrow makes too many white blood cells. ARIAD received approval to market Iclusig in December 2012 for patients with CML who no longer responded to available therapies. The price of Iclusig upon market entry was $115,000 per year.[1] Within a year, reports of serious side effects led the U.S. Food and Drug Administration (FDA) to request that ARIAD suspend sales of Iclusig and halt clinical trials.[2] Upon further review of clinical data, it was observed that one in four patients treated with Iclusig developed blood clots or narrowing of blood vessels, a far greater rate of these side effects than what was observed in ARIAD's pre-approval clinical trial data.[3]

In December 2013, FDA allowed ARIAD to resume selling Iclusig, but only to a smaller subset of patients for whom a genetic mutation made them resistant to other drugs available to treat CML. Additionally, FDA required ARIAD to (1) place new cardiovascular safety warnings on the drug's label; (2) implement a risk evaluation and mitigation strategy; and (3) conduct additional postmarket investigations.[4]

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[1] Adam Feuerstein, "How Ariad Pharma Used a Safety Problem to Jack Up a Cancer Drug's Price," *The Street* (Oct. 6, 2016) (online at https://www.thestreet.com/story/13844437/1/how-ariad-pharma-used-a-safety-problem-to-jack-up-the-price-of-a-cancer-drug.html).

[2] *Id. See also* U.S. Food and Drug Administration, "FDA Drug Safety Communication: FDA asks manufacturer of the leukemia drug Iclusig (ponatinib) to suspend marketing and sales" (Nov. 5, 2013) (online at http://www.fda.gov/Drugs/DrugSafety/ucm373040.htm).

[3] U.S. Food and Drug Administration, "FDA Drug Safety Communication: FDA investigating leukemia drug Iclusig (ponatinib) after increased reports of serious blood clots in arteries and veins" (Oct. 11, 2013) (online at http://www.fda.gov/Drugs/DrugSafety/ucm370945.htm). *See also* U.S. Food and Drug Administration, "FDA Drug Safety Communication: FDA requires multiple new safety measures for leukemia drug Iclusig; company expected to resume marketing" (Dec. 20, 2013) (online at http://www.fda.gov/Drugs/DrugSafety/ucm379554.htm).

[4] U.S. Food and Drug Administration, "FDA Drug Safety Communication: FDA requires multiple new safety measures for leukemia drug Iclusig; company expected to resume marketing" (Dec. 20, 2013) (online at http://www.fda.gov/Drugs/DrugSafety/ucm379554.htm).

Despite this new evidence showing the drug posed a far greater safety risk to patients than was known when the drug came on the market, ARIAD nonetheless raised the price of Iclusig several times over the subsequent four years to $199,000 per year from $115,000 per year.[5] Not only did ARIAD raise the price of Iclusig, but it reportedly took additional steps to further boost company profits by discontinuing sales of a two-month (60-tablet) supply of its 15 mg dose, and instead selling a 30-tablet supply of the same dose for the same price – effectively doubling the cost for patients.[6] We also seek your reply to reports that ARIAD discontinued sales of the 30 mg tablet of Iclusig, a common therapeutic dose, in an effort to require patients and insurers to pay twice as much for two 15 mg doses, another way to increase profits. These outrageous sales tactics indicate that ARIAD is more concerned with its profit than with its patients.

According to press reports, you joined ARIAD in January 2016 after ARIAD's largest shareholder Sarissa Capital Management, run by billionaire hedge fund manager Alex Denner, "successfully pushed for the ouster of CEO Harvey Berger," your predecessor.[7] Over your short tenure as CEO, the price of Iclusig has already jumped several more times to reach $16,561 per month, or nearly $199,000 per year.[8]

Your company has responded to concerns about the high price of Iclusig by arguing that the drug's clinical benefits, ARIAD's "significant investment in R&D," and its "commitment to the patient population" justify charging patients these outrageous prices.[9] In the interest of patients and taxpayers, we are interested in learning more about the impact that the escalating price and restrictions on product availability have had. Please provide the following documents and information from 2012 to the present:

(1) total gross and net revenues and profits and operating profits from the company's sales of this drug;

(2) the dates, quantities, purchasers, and prices paid for all sales of this drug;

(3) total expenses relating to the development and sales of this drug, including specific amounts for research and development, clinical trials, manufacturing, marketing and advertising, and purchases of active pharmaceutical ingredients, if applicable;

(4) sales contracts or purchase agreements for active pharmaceutical ingredients for this drug, including any agreements relating to exclusivity, if applicable;

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[5] Ed Silverman, "What Outrage? Ariad raises price of its leukemia drug four times so far this year," *STAT* (Oct. 7, 2016) (online at https://www.statnews.com/pharmalot/2016/10/07/ariad-riases-leukemia-drug-price).
[6] *Id.*
[7] Cynthia Koons, "Ariad Said to Name Panayiotopoulos CEO After Activist Push," *Bloomberg* (Dec. 17, 2015) (online at http://www.bloomberg.com/news/articles/2015-12-18/ariad-said-to-name-panayiotopoulos-ceo-after-activist-shakeup).
[8] Adam Feuerstein, "How Ariad Pharma Used a Safety Problem to Jack Up a Cancer Drug's Price," *The Street* (Oct. 6, 2016) (online at https://www.thestreet.com/story/13844437/1/how-ariad-pharma-used-a-safety-problem-to-jack-up-the-price-of-a-cancer-drug.html).
[9] Ed Silverman, "What Outrage? Ariad raises price of its leukemia drug four times so far this year," *STAT* (Oct. 7, 2016) (online at https://www.statnews.com/pharmalot/2016/10/07/ariad-riases-leukemia-drug-price).

(5) a description and valuation of the specific financial and non-financial factors that contributed to your company's decisions to increase the price of this drug;

(6) an explanation for why ARIAD discontinued offering the 60-tablet quantity of this drug and discontinued offering the 30 mg tablet dosage strength of this drug;

(7) any cost estimates, profit projections, or other analyses relating to the company's current and future sales of this drug, including any analyses related to safety concerns;

(8) a description of any patient assistance or coupon programs and information on the number of patients served, any tax deductions ARIAD has taken relating to these programs, and the value of the drugs provided under these programs;

(9) prices of this drug in all foreign countries or markets, including price information for the countries paying the highest and lowest prices; and

(10) the identity of company official(s) responsible for setting the prices of these drugs over the above time period.

Please provide the requested documents and information by November 4, 2016 to 2471 Rayburn House Office Building, Washington, D.C. 20515. If you have any questions, please contact Alexandra Golden of Representative Cummings' staff at (202) 225-5051 or Sophie Kasimow of Senator Sanders' staff at (202) 224-5141. We appreciate your attention and prompt reply.

Sincerely,

Elijah E. Cummings
United States Representative

Bernard Sanders
United States Senator