APPENDIX 1

Submission of trial results can be delayed by submitting one of two types of certificates. First, responsible parties may submit a certification of "initial approval", indicating a trial reached its primary completion date before the drug is initially approved, licensed, or cleared by FDA for any use. In this case, the results are due no later than 30 days post FDA approval, license or clearance. Second, a certification of "new use" can be filed indicating the "trial studies a new use of an FDA-approved drug… and the manufacturer of the drug, biologic, or device is the sponsor of the trial and has filed or will file within 1 year an application to FDA for approval or clearance of that use." In this case, the results are due either two years after the submission of the certification or 30 days after the below occurs, whichever occurs first:

a. The new use of the drug or device is approved, licensed, or cleared by FDA,
b. FDA issues a letter for the new use of the drug or device, such as a complete response letter,
c. The application or premarket notification for the new use is withdrawn without resubmission for no less than 210 days.

APPENDIX 2

Below is a list of the Active Ingredients for each of our analyzed drugs.

Aubagio: TERIFLUNOMIDE
Bosulif: BOSUTINIB MONOHYDRATE
Elelyso: TALIGLUCERASE ALFA
Eliquis: APIXABAN
Erivedge: VISMODEGIB
Inlyta: AXITINIB
MenHibrix: MENINGOCOCCAL GROUPS C AND Y AND HAEMOPHILUS B TETANUS TOXOID CONJUGATE VACCINE
Perjeta: PERTUZUMAB
Signifor: PASIREOTIDE DIASPARTATE
Sirturo: BEDAQUILINE FUMARATE
Stivarga: REGORAFENIB
Stribild: COBICISTAT; ELVITEGRAVIR; EMTRICITABINE; TENOFOVIR DISOPROXIL FUMARATE
Xeljanz: TOFACITINIB CITRATE
Zaltrap: ZIV-AFLIBERCEPT
Zioptan: TAFLUPROST