## 2018 CDER Fast Track Calendar Year Approvals\* Data as of 12/31/2018 Total of 33 Approvals

| Application<br>Number         Submission<br>Num           NDA 208910         ORIGI           NDA 208910         ORIGI           NDA 208700         ORIGI           NDA 208255         ORIGI           NDA 208255         ORIGI           NDA 210491         ORIGI           NDA 210491         ORIGI           NDA 210951         ORIGI           NDA 208855         ORIGI           BLA 761065         ORIGI           BLA 761065         ORIGI           NDA 209229         ORIGI           NDA 209229         ORIGI           NDA 209229         ORIGI           NDA 208627         ORIGI           NDA 210365         ORIGI           NDA 210589         ORIGI           NDA 209607         ORIGI           NDA 210923         ORIGI           NDA 211358         ORIGI           NDA 210607         ORIGI | NAL-1     FIRVANQ       INAL-1     LUTATHER       INAL-1     SYMFILO       INAL-1     SYMDEKO       INAL-1     ERLEADA       INAL-1     ERLEADA       INAL-1     TROGARZO       INAL-1     CRYSVITA       INAL-1     LUCEMYR       INAL-1     PALYNZIO       INAL-1     EPIDIOLEX       INAL-1     TPOXX       INAL-1     TIBSOVO | Established Name       P     VANCOMYCIN       HYDROCHLORIDE     177LI-       DOTA <sup>0</sup> -Tyr <sup>3</sup> -OCTREOTATE     177LI-       DOTA <sup>0</sup> -Tyr <sup>3</sup> -OCTREOTATE     EFAVIRENZ, LAMIVUDINE, AND TENOFOVIR DISOPROXIL       P     FUMARATE       DO     TEZACAFTOR/ IVACAFTOR       A     APALUTAMIDE       D     ABEMACICLIB       O     IBALIZUMAB-UIYK       A     LOFEXIDINE       Q     PEGVALIASE-PQPZ       X     CANNABIDIOL       TECOVIRIMAT   | Applicant         RXM THERAPEUTICS LLC         ADVANCED ACCELERATOR         APPLICATIONS USA INC         MYLAN PHARMACEUTICALS INC         VERTEX PHARMACEUTICALS INC         JANSSEN BIOTECH INC         ELI LILLY AND CO         THERATECHNOLOGIES INC         ULTRAGENYX<br>PHARAMCEUTICAL INC         BIOMARIN PHARMACEUTICAL INC         GW RESEARCH, LTD         SIGA TECHNOLOGIES INC         AGIOS PHARMACEUTICALS INC | Approval Date*  26-Jan-2018  26-Jan-2018  5-Feb-2018  12-Feb-2018  14-Feb-2018  26-Feb-2018  6-Mar-2018  17-Apr-2018  16-May-2018  24-May-2018  25-Jun-2018  13-Jul-2018 | Use<br>Treatment of Clostridium difficile-associated<br>diarrhea<br>Treatment of somatostatin receptor-positive<br>gastroenteropancreatic neuroendocrine tumors<br>including foregut, midgut, and hindgut neuroendocrine tumors<br>in adults<br>Treatment of HIV-1 infection in adult and pediatric patients<br>weighing at least 35 kg<br>Treatment of patients with cysic fibrosis (CF) aged 12 years<br>and older who are homozygous for the F508del mutation or<br>who have at least one mutation in the cysic fibrosis<br>transmembrane conductance regulator (CFTR) gene that is<br>responsive to tezacator/ivacaftor based on in vitro data<br>and/or clinical evidence<br>Treatment of patients with high risk non-metastatic castration<br>resistant prostate cancer<br>In combination with an aromatase inhibitor as initial endocrine<br>based therapy for the treatment of postmenopausal women<br>with homone receptor (HR)-positive, human epidermal<br>growth factor receptor 2 (HER2)-negative advanced or<br>metastatic breast cancer<br>Treatment of human immunodeficiency virus type 1 (HIV-1)<br>infection in heavity treatment-experienced adults with<br>multidrug resistant HIV-1 infection failing their current<br>antiertovirul regimen<br>Treatment of opioid withfawal symptoms to facilitate abrupt<br>opioid discontinuotin in adults<br>To reduce blod phenylalanine concentrations in adult<br>patients with phenylketonuria (PKU) who have uncontrolled<br>blod phenylalanine concentrations greater than 600<br>microm0/L, on existing management<br>Treatment of seizures associated with Dravet<br>wordmen in antients two voarses of ane an older<br>Treatment of patients with human smallpox disease |
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| NDA 208700         ORIGI           NDA 208255         ORIGI           NDA 208255         ORIGI           NDA 210491         ORIGI           NDA 210951         ORIGI           NDA 208855         ORIGI           NDA 208855         ORIGI           BLA 761065         ORIGI           NDA 209229         ORIGI           NDA 210365         ORIGI           NDA 210365         ORIGI           NDA 210365         ORIGI           NDA 210365         ORIGI           NDA 210589         ORIGI           NDA 210589         ORIGI           NDA 210923         ORIGI           NDA 210923         ORIGI           NDA 210589         ORIGI           NDA 210923         ORIGI           NDA 210507         ORIGI  | INAL-1 LUTATHER<br>INAL-1 SYMFILO<br>INAL-1 SYMDEKO<br>INAL-1 ERLEADA<br>INAL-1 VERZENIO<br>INAL-1 TROGARZO<br>INAL-1 CRYSVITA<br>INAL-1 LUCEMYR<br>INAL-1 PALYNZIO<br>INAL-1 PALYNZIO<br>INAL-1 TPOXX<br>INAL-1 TPOXX  | HYDROCHLORIDE       177Lu-<br>DOTA <sup>0</sup> -Tyr <sup>3</sup> -OCTREOTATE       EFAVIRENZ, LAMIVUDINE,<br>AND TENOFOVIR DISOPROXIL<br>FUMARATE       D     TEZACAFTOR/ IVACAFTOR       A     APALUTAMIDE       D     ABEMACICLIB       O     IBALIZUMAB-UIYK       A     LOFEXIDINE       A     LOFEXIDINE       Q     PEGVALIASE-PQPZ       X     CANNABIDIOL       TECOVIRIMAT   | ADVANCED ACCELERATOR<br>APPLICATIONS USA INC<br>MYLAN PHARMACEUTICALS INC<br>VERTEX PHARMACEUTICALS INC<br>JANSSEN BIOTECH INC<br>ELI LILLY AND CO<br>THERATECHNOLOGIES INC<br>ULTRAGENYX<br>PHARAMCEUTICAL INC<br>US WORLDMEDS LLC<br>BIOMARIN PHARMACEUTICAL INC<br>GW RESEARCH, LTD<br>SIGA TECHNOLOGIES INC  | 26-Jan-2018<br>5-Feb-2018<br>12-Feb-2018<br>14-Feb-2018<br>26-Feb-2018<br>6-Mar-2018<br>17-Apr-2018<br>16-May-2018<br>24-May-2018<br>25-Jun-2018                         | diarrhea<br>Treatment of somatostatin receptor-positive<br>gastroerlteropancreatic neuroendocrine tumors (GEP-NETs),<br>including foregut, midgut, and hindgut neuroendocrine tumors<br>in adults<br>Treatment of HIV-1 infection in adult and pediatric patients<br>weighing at least 35 kg<br>Treatment of patients with cystic fibrosis (CF) aged 12 years<br>and older who are homozyoguo for the F508del mutation or<br>who have at least one mutation in the cystic fibrosis<br>transmembrane conductance regulator (CFTR) gene that is<br>responsive to tezacator/invacatfor based on in vitro data<br>and/or clinical evidence<br>Treatment of patients with high risk non-metastatic castration<br>resistant prostate cancer<br>In combination with an aromatase inhibitor as initial endocrine<br>based therapy for the treatment of positive, human epidermal<br>growth factor receptor 2 (HER2)-negative advanced or<br>metastatic breast cancer<br>Treatment of human immunodeficiency virus type 1 (HIV-1)<br>infection in heavily treatment-experience adults with<br>multidrug resistant HIV-1 infection failing their current<br>antiretroviral regimen<br>Treatment of X-linked hypophosphatemia (XLH) in<br>adult and pediatric patients 1 year of age and older<br>Mingation of opioid withdrawal symptoms to facilitate abrupt<br>opioid discontinuation in adults<br>To reduce blood phenylalanine concentrations in adult<br>patients with phenylketonuic (FKU) who have uncontrolled<br>blood phenylalanine concentrations reater than 600<br>micromol/L on existing management<br>Treatment of patients two wears of ane and older<br>Mingation of patients with human smallphance dave                             |
| NDA 208255         ORIGI           NDA 210491         ORIGI           NDA 210951         ORIGI           NDA 210951         ORIGI           NDA 208855         ORIGI           BLA 761065         ORIGI           BLA 761065         ORIGI           NDA 209229         ORIGI           NDA 210365         ORIGI           NDA 210589         ORIGI           NDA 210589         ORIGI           NDA 210923         ORIGI           NDA 210923         ORIGI           NDA 210923         ORIGI           NDA 210607         ORIGI   | INAL-1 SYMFILO<br>INAL-1 SYMDEKO<br>INAL-1 ERLEADA<br>INAL-1 VERZENIO<br>INAL-1 TROGARZI<br>INAL-1 CRYSVITA<br>INAL-1 LUCEMYR<br>INAL-1 PALYNZIO<br>INAL-1 TPOXX<br>INAL-1 TIBSOVO  | Image: A constraint of the second | APPLICATIONS USA INC<br>MYLAN PHARMACEUTICALS INC<br>VERTEX PHARMACEUTICALS INC<br>JANSSEN BIOTECH INC<br>ELI LILLY AND CO<br>THERATECHNOLOGIES INC<br>ULTRAGENYX<br>PHARAMCEUTICAL INC<br>US WORLDMEDS LLC<br>BIOMARIN PHARMACEUTICAL INC<br>GW RESEARCH, LTD<br>SIGA TECHNOLOGIES INC  | 5-Feb-2018<br>12-Feb-2018<br>14-Feb-2018<br>26-Feb-2018<br>6-Mar-2018<br>17-Apr-2018<br>16-May-2018<br>24-May-2018<br>25-Jun-2018  | Treatment of somatostatin receptor-positive<br>gastroenteropancreatic neuroendocrine tumors (GEP-NETs),<br>including toregut, midgut, and hindgut neuroendocrine tumors<br>in adults<br>Treatment of HIV-1 infection in adult and pediatric patients<br>weighing at least 35 kg<br>Treatment of patients with cystic fibrosis (CF) aged 12 years<br>and older who are homozygous for the F508del mutation or<br>who have at least one mutation in the cystic fibrosis<br>transmembrane conductance regulator (CFTR) gene that is<br>responsive to tezacator/ivacaftor based on in vitro data<br>and/or clinical evidence<br>Treatment of patients with high risk non-metastatic castration<br>resistant prostate cancer<br>In combination with an aromatase inhibitor as initial endocrine<br>based therapy for the treatment of postmenopausal women<br>with hormone receptor (HR)-positive, human epidermal<br>growth factor receptor 2 (HER2)-negative advanced or<br>metastatic breast cancer<br>Treatment of human immunodeficiency virus type 1 (HIV-1)<br>infection in heavily treatment-experienced adults with<br>multidrug resistant HIV-1 infection failing their current<br>antiretroviral regimen<br>Treatment of opioid withrawal symptoms to facilitate abrupt<br>opioid discontinuation in adults<br>To reduce blood phenylalanine concentrations in adult<br>patients with phenylketonuria (PKU) who have uncontrolled<br>blood phenylalanine concentrations greater than 600<br>micromo/UL on existing mangement<br>Treatment of patients two wars of ane and older<br>Mitogation of patients with human smallops disease  |
| NDA 210491         ORIGI           NDA 210951         ORIGI           NDA 20955         ORIGI           NDA 208855         ORIGI           BLA 761065         ORIGI           BLA 761068         ORIGI           NDA 209229         ORIGI           NDA 209229         ORIGI           NDA 209229         ORIGI           NDA 20365         ORIGI           NDA 210365         ORIGI           NDA 210365         ORIGI           NDA 210589         ORIGI           NDA 209607         ORIGI           NDA 210923         ORIGI           NDA 211358         ORIGI           NDA 210607         ORIGI   | INAL-1 SYMDEKC<br>INAL-1 ERLEADA<br>INAL-1 VERZENIC<br>INAL-1 TROGARZI<br>INAL-1 CRYSVITA<br>INAL-1 LUCEMYR<br>INAL-1 PALYNZIC<br>INAL-1 PALYNZIC<br>INAL-1 TPOXX<br>INAL-1 TIBSOVO   | AND TENOFOVIR DISOPROXIL<br>FUMARATE       D     TEZACAFTOR/ IVACAFTOR       A     APALUTAMIDE       D     ABEMACICLIB       O     IBALIZUMAB-UIYK       A     BUROSUMAB-TWZA       A     LOFEXIDINE       D     PEGVALIASE-PQPZ       X     CANNABIDIOL       TECOVIRIMAT   | VERTEX PHARMACEUTICALS INC<br>JANSSEN BIOTECH INC<br>ELI LILLY AND CO<br>THERATECHNOLOGIES INC<br>ULTRAGENYX<br>PHARAMCEUTICAL INC<br>US WORLDMEDS LLC<br>BIOMARIN PHARMACEUTICAL INC<br>GW RESEARCH, LTD<br>SIGA TECHNOLOGIES INC   | 12-Feb-2018<br>14-Feb-2018<br>26-Feb-2018<br>6-Mar-2018<br>17-Apr-2018<br>16-May-2018<br>24-May-2018<br>25-Jun-2018  | Treatment of HIV-1 infection in adult and pediatric patients<br>weighing at least 35 kg<br>Treatment of patients with cystic fibrosis (CF) aged 12 years<br>and older who are homozygous for the F508del mutation or<br>who have at least one mutation in the cystic fibrosis<br>transmembrane conductance regulator (CFTR) gene that is<br>responsive to texacator/ivacatfor based on in vitro data<br>and/or clinical evidence<br>Treatment of patients with high risk non-metastatic castration<br>resistant prostate cancer<br>In combination with an aromatase inhibitor as initial endocrine<br>based therapy for the treatment of postmenopausal women<br>with hormone receptor (HR)-positive, human epidermal<br>growth factor receptor 2 (HER2)-negative advanced or<br>metastatic breast cancer<br>Treatment of human immunodeficiency virus type 1 (HIV-1)<br>infection in heavily treatment-experienced adults with<br>multidrug resistant HIV-1 infection failing their current<br>antiretoviral regimen<br>Treatment of x-linked hypophosphatemia (XLH) in<br>adult and pediatric patients 1 year of age and older<br>Mitigation of opioid withdrawal symptoms to facilitate abrupt<br>opioid discontinuation in adults<br>To reduce blood phenylalanine concentrations in adult<br>patients with phenylketonuic (PKU) who key uncontrolled<br>blood phenylalanine concentrations greater than 600<br>micromoVL on existing management<br>Treatment of patients with human smallpox disease  |
| NDA 210951         ORIGI           NDA 208855         ORIGI           NDA 208855         ORIGI           BLA 761065         ORIGI           BLA 761068         ORIGI           NDA 209229         ORIGI           BLA 761079         ORIGI           NDA 210365         ORIGI           NDA 210365         ORIGI           NDA 210365         ORIGI           NDA 210589         ORIGI           NDA 210589         ORIGI           NDA 210923         ORIGI           NDA 211358         ORIGI           NDA 210607         ORIGI   | INAL-1 ERLEADA<br>INAL-1 VERZENIC<br>INAL-1 TROGARZI<br>INAL-1 CRYSVITA<br>INAL-1 LUCEMYR<br>INAL-1 PALYNZIC<br>INAL-1 PALYNZIC<br>INAL-1 TPOXX<br>INAL-1 TIBSOVO   | A APALUTAMIDE A APALUTAMIDE A BUROSUMAB-UIYK A BUROSUMAB-TWZA A LOFEXIDINE A LOFEXIDINE A CANNABIDIOL TECOVIRIMAT  | JANSSEN BIOTECH INC<br>ELI LILLY AND CO<br>THERATECHNOLOGIES INC<br>ULTRAGENYX<br>PHARAMCEUTICAL INC<br>US WORLDMEDS LLC<br>BIOMARIN PHARMACEUTICAL INC<br>GW RESEARCH, LTD<br>SIGA TECHNOLOGIES INC   | 14-Feb-2018<br>26-Feb-2018<br>6-Mar-2018<br>17-Apr-2018<br>16-May-2018<br>24-May-2018<br>25-Jun-2018   | and older who are homozygous for the F508del mutation or<br>who have at least one mutation in the cystic fibrosis<br>transmembrane conductance regulator (CFTR) gene that is<br>responsive to tezacator/ivacaftor based on in vitro data<br>and/or clinical evidence.<br>In combination with an aromatase inhibitor as initial endocrine<br>based therapy for the treatment of postmenopausal women<br>with hormone receptor (HR)-positive, human epidermal<br>growth factor receptor 2 (HER2)-negative advanced or<br>metastatic breast cancer<br>Treatment of human immunodeficiency virus type 1 (HIV-1)<br>infection in heavily treatment-experienced adults with<br>multidrug resistant HIV-1 infection failing their current<br>antiretroviral regimen<br>Treatment of X-linked hypophosphatemia (XLH) in<br>adult and pediatric patients 1 year of age and older<br>Mitigation of opioid withdrawal symptoms to facilitate abrut<br>opioid discontinuation in adults<br>To reduce blood phenylalanine concentrations in adult<br>patients with phenyletonuria (PKU) who have uncontrolled<br>blood phenylalanine concentrations greater than 600<br>micromo/UL on existing management<br>Treatment of seizures associated with Dravet<br>syndrome in patients two years of ane and older.   |
| NDA 208855         ORIGI           BLA 761065         ORIGI           BLA 761068         ORIGI           NDA 209229         ORIGI           NDA 209229         ORIGI           NDA 210365         ORIGI           NDA 208627         ORIGI           NDA 210365         ORIGI           NDA 211192         ORIGI           NDA 209607         ORIGI           NDA 210923         ORIGI           NDA 211358         ORIGI           NDA 210607         ORIGI   | INAL-1 VERZENIC<br>INAL-1 TROGARZI<br>INAL-1 CRYSVITA<br>INAL-1 LUCEMYR<br>INAL-1 PALYNZIC<br>INAL-1 PALYNZIC<br>INAL-1 TPOXX<br>INAL-1 TIBSOVO   | D     ABEMACICLIB       O     IBALIZUMAB-UIYK       A     BUROSUMAB-TWZA       A     LOFEXIDINE       Q     PEGVALIASE-PQPZ       X     CANNABIDIOL       TECOVIRIMAT  | ELI LILLY AND CO<br>THERATECHNOLOGIES INC<br>ULTRAGENYX<br>PHARAMCEUTICAL INC<br>US WORLDMEDS LLC<br>BIOMARIN PHARMACEUTICAL INC<br>GW RESEARCH, LTD<br>SIGA TECHNOLOGIES INC  | 26-Feb-2018<br>6-Mar-2018<br>17-Apr-2018<br>16-May-2018<br>24-May-2018<br>25-Jun-2018  | resistant prostate cancer<br>In combination with an aromatase inhibitor as initial endocrine<br>based therapy for the treatment of postmenopausal women<br>with hormone receptor (HR)-positive, human epidermal<br>growth factor receptor 2 (HER2)-negative advanced or<br>metastatic breast cancer<br>Treatment of human immunodeficiency virus type 1 (HIV-1)<br>infection in heavily treatment-experienced adults with<br>multidrug resistant HIV-1 infection failing their current<br>antiretroviral regimen<br>Treatment of X-linked hypophosphatemia (XLH) in<br>adult and pediatric patients 1 year of age and older<br>Mitigation of opioid withfrawal symptoms to facilitate abrut<br>opioid discontinuation in adults<br>To reduce blood phenylalanite concentrations in adult<br>patients with phenylketonuria (PKU) who have uncontrolled<br>blood phenylalanite concentrations greater than 600<br>micromo/L on existing mangement<br>Treatment of patients twin wears of ane and older   |
| BLA 761065         ORIGI           BLA 761068         ORIGI           BLA 761068         ORIGI           NDA 209229         ORIGI           BLA 761079         ORIGI           NDA 210365         ORIGI           NDA 208627         ORIGI           NDA 210365         ORIGI           NDA 211192         ORIGI           NDA 210589         ORIGI           NDA 209607         ORIGI           NDA 210923         ORIGI           NDA 211358         ORIGI           NDA 210607         ORIGI  | INAL-1 TROGARZI<br>INAL-1 CRYSVIT/<br>INAL-1 LUCEMYR<br>INAL-1 PALYNZIC<br>INAL-1 PALYNZIC<br>INAL-1 TPOXX<br>INAL-1 TIBSOVO  | O     IBALIZUMAB-UIYK       A     BUROSUMAB-TWZA       A     LOFEXIDINE       Q     PEGVALIASE-PQPZ       X     CANNABIDIOL       TECOVIRIMAT  | THERATECHNOLOGIES INC<br>ULTRAGENYX<br>PHARAMCEUTICAL INC<br>US WORLDMEDS LLC<br>BIOMARIN PHARMACEUTICAL INC<br>GW RESEARCH, LTD<br>SIGA TECHNOLOGIES INC  | 6-Mar-2018<br>17-Apr-2018<br>16-May-2018<br>24-May-2018<br>25-Jun-2018   | In combination with an aromatase inhibitor as initial endocrine<br>based therapy for the treatment of postmenopausal women<br>with hormone receptor (HR-positive, human epidermal<br>growth factor receptor 2 (HER2)-negative advanced or<br>metastatic breast cancer<br>Treatment of human immunodeficiency virus type 1 (HIV-1)<br>infection in heavily treatment-experienced adults with<br>multidrug resistant HIV-1 infection failing their current<br>antiretroviral regimen<br>Treatment of X-linked hypophosphatemia (XLH) in<br>adult and pediatric patients 1 year of age and older<br>Mitigation of opioid withdrawal symptoms to facilitate abrupt<br>opioid discontinuation in adults<br>To reduce blood phenylatanine concentrations in adult<br>patients with phenylketonuria (PKU) who have uncontrolled<br>blood phenylalanine concentrations greater than 600<br>micromo/U. on existing management<br>Treatment of seizures associated with Dravet<br>syndrome in patients two years of ane and older  |
| BLA 761068         ORIGI           NDA 209229         ORIGI           BLA 761079         ORIGI           BLA 761079         ORIGI           NDA 210365         ORIGI           NDA 210365         ORIGI           NDA 211192         ORIGI           NDA 210589         ORIGI           NDA 209607         ORIGI           NDA 210923         ORIGI           NDA 211358         ORIGI           NDA 210607         ORIGI  | INAL-1 CRYSVITA<br>INAL-1 LUCEMYR<br>INAL-1 PALYNZIG<br>INAL-1 EPIDIOLE2<br>INAL-1 TPOXX<br>INAL-1 TIBSOVO  | A BUROSUMAB-TWZA<br>A LOFEXIDINE<br>D PEGVALIASE-PQPZ<br>X CANNABIDIOL<br>TECOVIRIMAT  | ULTRAGENYX<br>PHARAMCEUTICAL INC<br>US WORLDMEDS LLC<br>BIOMARIN PHARMACEUTICAL INC<br>GW RESEARCH, LTD<br>SIGA TECHNOLOGIES INC   | 17-Apr-2018<br>16-May-2018<br>24-May-2018<br>25-Jun-2018   | infection in heavily treatment-experienced adults with<br>multidrug resistant HIV-1 infection failing their current<br>antiretroviral regimen<br>Treatment of X-linked hypophosphatemia (XLH) in<br>adult and pediatric patients 1 year of age and older<br>Mitigation of opioid withdrawal symptoms to facilitate abrupt<br>opioid discontinuation in adults<br>To reduce blood phenylalanine concentrations in adult<br>patients with phenylketonuria (PKU) who have uncontrolled<br>blood phenylalanine concentrations greater than 600<br>micromo/U. on existing management<br>Treatment of seizures associated with Dravet<br>syndrome in patients two years of ane and older<br>Treatment of patients with human smallpox disease  |
| NDA 209229         ORIGI           BLA 761079         ORIGI           NDA 210365         ORIGI           NDA 210365         ORIGI           NDA 210365         ORIGI           NDA 211192         ORIGI           NDA 210589         ORIGI           NDA 209607         ORIGI           NDA 210923         ORIGI           NDA 211358         ORIGI           NDA 210607         ORIGI   | INAL-1 LUCEMYR<br>INAL-1 PALYNZIG<br>INAL-1 EPIDIOLE2<br>INAL-1 TPOXX<br>INAL-1 TIBSOVO   | A LOFEXIDINE PEGVALIASE-PQPZ X CANNABIDIOL TECOVIRIMAT   | PHARAMCEUTICAL INC<br>US WORLDMEDS LLC<br>BIOMARIN PHARMACEUTICAL INC<br>GW RESEARCH, LTD<br>SIGA TECHNOLOGIES INC   | 16-May-2018<br>24-May-2018<br>25-Jun-2018  | Treatment of X-linked hypophosphatemia (XLH) in<br>adult and pediating patients 1 year of age and older<br>Mitigation of opioid withdrawal symptoms to facilitate abrupt<br>opioid discontinuation in adults<br>To reduce blood phenylalanine concentrations in adult<br>patients with phenylateronuria (PKU) who have uncontrolled<br>blood phenylalanine concentrations greater than 600<br>micromo/U. on existing management<br>Treatment of seizures associated with Dravet<br>syndrome in patients two years of ane and older<br>Treatment of patients with human smallpox disease  |
| BLA 761079         ORIGI           NDA 210365         ORIGI           NDA 208627         ORIGI           NDA 211192         ORIGI           NDA 210589         ORIGI           NDA 209607         ORIGI           NDA 210923         ORIGI           NDA 211358         ORIGI           NDA 210923         ORIGI           NDA 210923         ORIGI  | INAL-1 PALYNZIG<br>INAL-1 EPIDIOLE2<br>INAL-1 TPOXX<br>INAL-1 TIBSOVO   | PEGVALIASE-PQPZ     CANNABIDIOL     TECOVIRIMAT  | US WORLDMEDS LLC<br>BIOMARIN PHARMACEUTICAL INC<br>GW RESEARCH, LTD<br>SIGA TECHNOLOGIES INC   | 24-May-2018<br>25-Jun-2018   | Mitigation of opioid withdrawal symptoms to facilitate abrupt<br>opioid discontinuation in adults<br>To reduce blood phenylatanine concentrations in adult<br>patients with phenylketonuria (PKU) who have uncontrolled<br>blood phenylalanine concentrations greater than 600<br>micromo/U. on existing management<br>Treatment of seizures associated with Dravet<br>syndrome in patients two years of ane and older<br>Treatment of patients with human smallpox disease  |
| BLA 761079         ORIGI           NDA 210365         ORIGI           NDA 208627         ORIGI           NDA 211192         ORIGI           NDA 210589         ORIGI           NDA 209607         ORIGI           NDA 210923         ORIGI           NDA 211358         ORIGI           NDA 210923         ORIGI   | INAL-1 PALYNZIG<br>INAL-1 EPIDIOLE2<br>INAL-1 TPOXX<br>INAL-1 TIBSOVO   | PEGVALIASE-PQPZ     CANNABIDIOL     TECOVIRIMAT  | BIOMARIN PHARMACEUTICAL INC<br>GW RESEARCH, LTD<br>SIGA TECHNOLOGIES INC   | 25-Jun-2018  | To reduce blood phenylalanine concentrations in adult<br>patients with phenylketonuria (PKU) who have uncontrolled<br>blood phenylalanine concentrations greater than 600<br>micromol/L on existing management<br>Treatment of seizures associated with Dravet<br>swnfrome in patients two years of ane and older<br>Treatment of patients with human smallox disease  |
| NDA 208627         ORIGI           NDA 211192         ORIGI           NDA 2110589         ORIGI           NDA 209607         ORIGI           NDA 210923         ORIGI           NDA 211358         ORIGI           NDA 210607         ORIGI  | INAL-1 TPOXX<br>INAL-1 TIBSOVO  | TECOVIRIMAT  | SIGA TECHNOLOGIES INC  |  | syndrome in patients two years of age and older<br>Treatment of patients with human smallpox disease   |
| NDA 211192         ORIGI           NDA 210589         ORIGI           NDA 209607         ORIGI           NDA 210923         ORIGI           NDA 211358         ORIGI           NDA 210607         ORIGI  | INAL-1 TIBSOVO  |  |  | 13-Jul-2018  | Treatment of patients with human smallpox disease  |
| NDA 210589         ORIGI           NDA 209607         ORIGI           NDA 210923         ORIGI           NDA 211358         ORIGI           NDA 210607         ORIGI   |   | ) IVOSIDENIB   | AGIOS PHARMACEUTICALS INC  |  | caused by variola virus  |
| NDA 209607         ORIGI           NDA 210923         ORIGI           NDA 211358         ORIGI           NDA 210607         ORIGI  | NAL-1 OMEGAVE   |  |  | 20-Jul-2018  | Treatment of adult patients with relapsed or refractory acute<br>myeloid leukemia (AML) with a susceptible isocitrate<br>dehydrogenase-1(IDH1) mutation as detected by an FDA-<br>approved test  |
| NDA 210923         ORIGI           NDA 211358         ORIGI           NDA 210607         ORIGI   |   | N FISH OIL TRIGLYCERIDES   | FRESENIUS KABI USA LLC   | 27-Jul-2018  | A source of calories and fatty acids in pediatric patients with<br>parenteral nutrition-associated cholestasis (PNAC)  |
| NDA 211358 ORIGI<br>NDA 210607 ORIGI   | INAL-1 AZEDRA   | IOBENGUANE I 131   | PROGENICS PHARMACEUTICALS<br>INC   | 30-Jul-2018  | parterinteral multition reasociated informations (INRC)<br>Treatment of adult and pediatric patients 12 years and older<br>with iobenguane scan positive, unresectable, locally<br>advanced or metastatic pheochromocytoma or<br>paraganglioma who require systemic anticancer therapy   |
| NDA 210607 ORIGI   | INAL-1 MULPLET  | A LUSUTROMBOPAG  | SHIONOGI INC   | 31-Jul-2018  | Treatment of thrombocytopenia in adult patients with chronic<br>liver disease who are scheduled to undergo a procedure   |
|  | INAL-1 ORKAMB   | I LUMACAFTOR/ IVACAFTOR  | VERTEX PHARMACEUTICALS INC   | 7-Aug-2018   | Treatment of cystic fibrosis (CF) in patients 2 years and<br>older, homozygous for the F508del-cystic fibrosis<br>transmembrane conductance regulator (CFTR) mutation in<br>the CFTR gene  |
| NDA 210922 ORIGI   | INAL-1 ARAKODA  | A TAFENOQUINE  | 60 DEGREES<br>PHARMACEUTICALS LLC  | 8-Aug-2018   | For the prophylaxis of malaria in patients 18 years<br>and older   |
|  | INAL-1 ONPATTR  | O PATISIRAN  | ALNYLAM<br>PHARMACEUTICALS INC   | 10-Aug-2018  | Treatment of the polyneuropathy of hereditary<br>transthyretin-mediated amyloidosis in adults  |
| NDA 208623 ORIGI   | INAL-1 GALAFOLI   | D MIGALASTAT   | AMICUS THERAPEUTICS U.S INC  | 10-Aug-2018  | Treatment of adults with a confirmed diagnosis of Fabry<br>disease and an amenable galactosidase alpha gene<br>(GLA) variant based on in vitro assay data  |
| BLA 761094 ORIGI   | INAL-1 OXERVAT  | E CENEGERMIN-BKBJ  | DOMPE FARMACEUTICI S.P.A.  | 22-Aug-2018  | Treatment of neurotrophic keratitis  |
| BLA 761090 ORIGI   | INAL-1 TAKHZYRO   | O LANADELUMAB-FLYO   | DYAX CORP  | 23-Aug-2018  | Prophylaxis to prevent attacks of hereditary angioedema<br>(HAE) in patients 12 years and older  |
| NDA 211109 ORIGI   | INAL-1 XERAVA   | ERAVACYCLINE   | TETRAPHASE<br>PHARMACEUTICALS INC  | 27-Aug-2018  | Treatment of complicated intra-abdominal infections<br>in patients 18 years of age and older   |
| BLA 761104 ORIGI   | INAL-1 LUMOXIT  | MOXETUMOMAB PASUDOTOX-<br>TDFK   | ASTRAZENECA AB   | 13-Sep-2018  | Treatment of adult patients with relapsed or refractory hairy<br>cell leukemia (HCL) who received at least two prior systemic<br>therapies, including treatment with a purine nucleoside<br>analog (PNA)   |
| NDA 211155 ORIGI   | INAL-1 COPIKTRA   | A DUVELISIB  | VERASTEM INC   | 24-Sep-2018  | Treatment of adult patients with relapsed or refractory<br>follicular lymphoma (FL) after at least two<br>prior systemic therapies   |
| NDA 211155 ORIGI   | INAL-2 COPIKTRA   | A DUVELISIB  | VERASTEM INC   | 24-Sep-2018  | Treatment of adult patients with relapsed or refractory<br>chronic lymphocytic leukemia (CLL) or small lymphocytic<br>lymphoma (SLL) after at least<br>two prior therapies   |
| NDA 207356 ORIGI   | INAL-1 ARIKAYCE   | E AMIKACIN LIPOSOME INHALATION<br>SUSPENSION   | INSMED INC   | 28-Sep-2018  | Treatment of Mycobacterium avium complex (MAC) lung<br>disease as part of a combination antibacterial drug regimen<br>in patients who do not achieve negative sputtum cultures after<br>a minimum of 6 consecutive months of a multidrug<br>background regimen therapy for use in adults who have<br>limited or no alternative treatment options   |
| NDA 209816 ORIGI   | INAL-1 NUZYRA   | OMADACYCLINE   | PARATEK PHARMACEURICALS<br>INC   | 2-Oct-2018   | Treatment of Community-Acquired<br>Bacterial Pneumonia (CABP) and Acute Bacterial Skin and<br>Skin Structure Infections (ABSSSI)<br>in adults due to the designated susceptible bacteria   |
| NDA 209817 ORIGI   |   | OMADACYCLINE   | PARATEK PHARMACEURICALS<br>INC   | 2-Oct-2018   | Treatment of Community-Acquired<br>Bacterial Pneumonia (CABP) and Acute Bacterial Skin and<br>Skin Structure Infections (ABSSSI)<br>in adults due to the designated susceptible bacteria   |
| BLA 761092 ORIGI   | INAL-1 NUZYRA   | I ELAPEGADEMASE-LVLR   | LEADIANT BIOSCIENCES INC   | 5-Oct-2018   | Treatment of Adenosine Deaminase-Severe<br>Combined Immunodeficiency (ADA-SCID)  |
| NDA 211172 ORIGI   |   |  | AKCEA THERAPEUTICS INC   | 5-Oct-2018   | Treatment of the polyneuropathy of hereditary  |
| NDA 210910 ORIGI   | INAL-1 REVCOVI  | I INOTERSEN  |  | 16-Nov-2018  | transthyretin-mediated amyloidosis in adults<br>Treatment of travelers' diarrhea caused by   |

| NDA 211349 | ORIGINAL-1 | XOSPATA | GILTERITINIB | ASTELLAS PHARMA US INC | 28-Nov-2018 | Treatment of adult patients who have relapsed or refractory<br>acute myeloid leukemia (AML) with a FMS-like tyrosine<br>kinase 3 (FLT3) mutation as detected by an FDA-approved<br>test |
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\* NOTE: Approvals with Fast Track granted because the drug was qualified as a PEPFAR drug are excluded