

Pharmaceutical Pipeline – Key Events in 2019*

Potential Approvals US/EU

ERLEADA® (apalutamide)	– Non-metastatic prostate cancer (EU) ✓ – Metastatic castrate sensitive prostate cancer (TITAN) (US) ✓
BALVERSA™ (erdafitinib)	– Urothelial cancer (US) ✓
SPRAVATO™ (esketamine nasal spray)	– Treatment-resistant depression (US ✓ / EU)
STELARA®	– Ulcerative Colitis (US / EU) ✓
XARELTO®	– VTE prevention medically ill patients (US) ✓
IMBRUVICA®	– Frontline CLL combo w/obinutuzumab (US / EU) ✓ – Waldenström's Macroglobulinemia in combo w/rituximab (EU) ✓
TREMFYA®	– Psoriasis Patient-Controlled Injector (US) ✓
DARZALEX®	– Frontline Multiple Myeloma transplant ineligible in combo w/ lenalidomide and low dose dexamethasone (MAIA) (US) ✓ – Frontline Multiple Myeloma transplant (CASSIOPEIA) (US) ✓
INVOKANA®	– Treatment of Diabetic Nephropathy in adults with T2DM (US) ✓
rilpivrine long acting maintenance	– HIV (US)

Planned Submissions US/EU

rilpivrine long acting maintenance	– HIV (US / EU) ✓
SPRAVATO™ (esketamine nasal spray)	– Major Depressive Disorder who have active ideation with intent (US) ✓
DARZALEX®	– Frontline Multiple Myeloma transplant ineligible in combo w/ lenalidomide and low dose dexamethasone (MAIA) (US / EU) ✓ – Frontline Multiple Myeloma transplant (CASSIOPEIA) (US / EU) ✓ – Subcutaneous Formulation in patients with relapsed or refractory multiple myeloma (COLUMBA) (US / EU) ✓
ERLEADA® (apalutamide)	– Metastatic castrate sensitive prostate cancer (TITAN) (US / EU) ✓
INVOKANA®	– Treatment of Diabetic Nephropathy in adults with T2DM (US / EU) ✓
TREMFYA®	– Psoriatic Arthritis (US ✓ / EU)

✓ = Achieved

Potential Clinical Data Presentations

Phase 3

INVOKANA®	– Treatment of Diabetic Nephropathy in adults with T2DM (CREDENCE) ✓
STELARA®	– Ulcerative Colitis (UNIFI) ✓
Rilpivrine long Acting Maintenance	– HIV (ATLAS / FLAIR) ✓
TREMFYA®	– Psoriatic Arthritis (DISCOVER 1 & 2)
ERLEADA® (apalutamide)	– Metastatic castrate sensitive prostate cancer (TITAN) ✓
SPRAVATO™ (esketamine)	– Major Depressive Disorder who have active suicidal ideation with intent (ASPIRE I, ASPIRE II) ✓
DARZALEX®	– Subcutaneous Formulation in patients with relapsed or refractory multiple myeloma (COLUMBA) ✓ – Frontline Multiple Myeloma transplant (CASSIOPEIA) ✓
UPTRAVI®	– Pulmonary arterial hypertension IV (AC-065A309) ✓ – Pulmonary arterial hypertension (GRIPHON) ✓
Ponesimod	– Monotherapy for Multiple Sclerosis (OPTIMUM) ✓

Potential Clinical Data Presentations

Phase 2

DARZALEX®	– Subcutaneous formulation in combination with standard multiple myeloma treatments (PLEIADES)
HIV Vaccine	– HIV (ASCENT) ✓
Niraparib	– L3 Metastatic Castration-Resistant Prostate Cancer (GALAHAD) ✓