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US FDA approval tracker: several early decisions in May

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Last month the FDA greenlit four oncology approvals early and the first GnRH antagonist in uterine fibroids.

The US FDA approved four therapies early last month, all in cancer indications. One was Deciphera's Qinlock, approved three months early in gastrointestinal stromal tumours as a fourth line treatment. On the very same day Blueprint's competing project Ayvakit received a complete response letter, as expected, in the wake of the failure of the pivotal Voyager study.

Qinlock's real potential lies in earlier lines of therapy and a second-line study should readout next year. Ayvakit meanwhile looks like it will be limited to a niche group of patients with specific mutations, where it is already approved.

Another early win was Bristol Myers Squibb's Opdivo/Yervoy/chemo triplet in front-line lung cancer. The approval was based on the Checkmate-9LA study, and came despite ongoing questions around what Yervoy brings to the regimen, given its known toxicities.

Earlier in the month Opdivo plus Yervoy was approved in ≥1% PD-L1 expressers; Merck & Co's Keytruda can already be used as a monotherapy in these patients, and a Keytruda/chemo combo is approved in all-comers.

Lastly, two targeted therapies were greenlit early, Eli Lilly's Ret inhibitor Retevmo and Novartis's Met inhibitor Tabrecta, however both come with safety warnings.

Retevmo, which Lilly gained through its Loxo acquisition, was approved in advanced Ret-driven lung and thyroid cancers. The label includes warnings about QTc prolongation, hypersensitivity, and haemorrhagic events; analysts have noted that these toxicities have not been reported with Blueprint's rival Ret inhibitor, pralsetinib.

Pralsetinib is due to hear on US approval in lung cancer in November, and Blueprint plans to file in thyroid cancer this month.

Novartis's Tabrecta meanwhile was greenlit early for metastatic NSCLC with Met exon 14 skipping. The label includes a precaution about interstitial lung disease /pneumonitis, which occurred in 4.5% of patients in the phase II Geometry mono-1 study, with 1.8% experiencing Grade 3 side effects.

Notable first-time US approval decisions in May			
Project	**Company**	**2026e sales ($m)**	**Outcome**
Qinlock (ripretinib)	Deciphera	1,311	Approved (early 3 months)
Retevmo (selpercatinib)	Eli Lilly	1,172	Approved (early ~2 months)
Ayvakit	Blueprint Medicines	918	CRL
Phexxi (Amphora vaginal pH regulator)	Evofem biosciences	541	Approved
Oriahnn (Orilissa/elagolix)	Abbvie/Neurocrine	510	Approved
Tabrecta (capmatinib)	Novartis	355	Approved (early ~2 months)
Kynmobi (apomorphine sublingual film/APL-130277)	Sunovion/Aquestive Therapeutics	189	Approved
Dasotraline/SEP-225289	Sumitomo Dainippon Pharma	119	NDA withdrawn
Zilxi (FMX103/minocycline)	Menlo Therapeutics	112	Approved
Intravenous artesunate	Amivas	-	Approved
Cerianna (fluoroestradiol F 18)	Petnet Solutions/Zionexa	-	Approved
Tauvid (flortaucipir F 18)	Eli Lilly/Avid Radiopharmaceuticals	-	Approved
Sources: EvaluatePharma, Go or no go? Oncology dominates upcoming decisions			

Restrictions

Oncology aside, Abbvie's Oriahnn became the first approved GnRH receptor antagonist for uterine fibroids at the end of May. However, strict language surrounding contraindications could potentially limit Oriahnn's use, and indeed other projects in the GnRH class, according to SVBLeerink analysts.

Those advised against using the drug include women with an increased risk of blood clots, and those over 35 who smoke or have uncontrolled hypertension.

Oriahnn's label discloses two thrombotic events in the phase III program that were not discussed previously; one thrombosis in the calf and a pulmonary embolism. It is probable that these events were caused by the hormone add-back therapy (ABT) needed to counteract the menopause-like symptoms associated with GnRH inhibition.

ABT carries its own risks and is not advised in patients with high BMI, diabetes and cardiovascular disease. Nonetheless, a contraindication in smokers for Oriahnn was not expected by analysts.

No thromboembolic signals have been disclosed from competitors Myovant or Obseva to date. Myovant's relugolix in combination with ABT was filed in uterine fibroids this week, while Obseva is also developing a low dose version of its antagonist linzagolix without ABT.

Obseva hopes that excluding ABT will open up linzagolix as a first-line treatment, although the project has safety issues of its own in terms of bone mineral density loss.

Supplementary and other notable approval decisions in May			
Product	**Company**	**Indication (clinical trial)**	**Outcome**
Alunbrig	Takeda	IL ALK positive NSCLC (Alta -1L)	Approved
Darzalex Faspro (subcutaneous Darzalex)	J&J	Multiple myeloma (Columba MMY3012)	Approved
Dupixent	Sanofi	Atopic dermatitis in children aged 6 to 11 years	Approved
Farxiga	Astrazeneca	Reduce the risk of CV death or the worsening of heart failure in adults with HFrEF with and without type 2 diabetes (Dapa-HF)	Approved
Icosapent ethyl capsules (generic Vascepa)q	Hikma	To reduce the risk of cardiovascular events among adults with elevated triglyceride levels	Approved
Lynparza	Astrazeneca	mCRPC and germline or somatic HRR mutations (Profound)	Approved
Lynparza + Avastin	Astrazeneca	Advanced ovarian cancer maintenance with Avastin (Paola-1)	Approved
Opdivo + Yervoy	Bristol Myers Squibb	1L NSCLC without chemo (Checkmate-227)	Approved
Opdivo + Yervoy + chemo	Bristol Myers Squibb	1L NSCLC (Checkmate-9LA)	Approved (early 3 months)
Pomalyst	Bristol Myers Squibb	Adult patients with AIDS-related Kaposi sarcoma	Approved
Rubraca	Clovis	BRCA1/2-mutant recurrent mCRPC (Triton2)	Approved
Tecentriq	Roche	Monotherapy 1L NSCLC with high PD-L1 expression (Impower110)	Approved
Tecentriq + Avastin	Roche	Unresectable or metastatic hepatocellular carcinoma who have not received prior systemic therapy (IMbrave150)	Approved
Vesicare LS	Astellas	Neurogenic detrusor overactivity in paediatric patients	Approved
Sources: EvaluatePharma, Go or no go? Oncology dominates upcoming decisions			