COMMUNICATION

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PLEASE REVIEW

Drug Information

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate the latest up-to-date drug information.

Drug Information:

Remember that medical literature is dynamic and is continuously changing as new scientific knowledge is developed. We exhort the frequent revision of treatment guidelines to assure that your recommendations are consistent with the most updated information.

It is our priority to offer high-quality services and support practices for health promotion and diseases prevention. If you have any questions or wish to have more information regarding this document, you can call us directly or view PharmPix communications online.

QUESTIONS

Call us at 787-522-5252, ext. 220

Access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

15 Potential Blockbusters for 2023

In their annual Drugs to Watch report[1], analysts at market research firm Clarivate identified 15 treatments that demonstrate promising advancements including a broad spectrum of therapeutic developments for rare diseases and tough-to-treat conditions including HIV, Parkinson's disease, Crohn's disease, alopecia, multiple myeloma, and breast cancer. These drugs are forecast to become blockbusters within 5 years and/or to transform treatment paradigms.

Drugs to Watch:

1. **Bimzelx™ (bimekizumab)** (not yet approved by the FDA)
    a. **Indication:** Moderate to severe plaque psoriasis
    b. **Additional Information:** As the first dual-specific IL-17 A/F inhibitor to treat plaque psoriasis, bimekizumab could be more effective than inhibitors of IL-17A only at reducing skin and joint inflammation as well as pathological bone formation, which are the primary contributors to the symptomatic burden of psoriasis and with fewer side effects than some current treatment options, including a pan-IL-17 inhibitor.
2. **Capivasertib** (not yet approved by the FDA)
    a. **Indication:** Breast cancer
    b. **Additional Information:** Capivasertib is a novel, highly potent, selective ATP-competitive pan-AKT kinase inhibitor that exerts similar activity against the three isoforms AKT1, AKT2 and AKT3. Positive data have emerged from early-phase trials and several phase 3 trials are now underway.
3. **Duvroq™ (daprodustat)**
    a. **Indication:** Chronic kidney disease (CKD)-related anemia
    b. **Additional Information:** Daprodustat belongs to a novel class of oral treatments for CKD-related anemia. It is expected to differentiate itself from entrenched, injectable erythropoiesis-stimulating agents (ESAs) by its safety profile, efficacy, and oral administration. As such, it will help fill the gap in safe treatments for this growing patient population.
4. **Sotyktu™ (deucravacitinib)**
    a. **Indication:** Plaque psoriasis
    b. **Additional Information:** As a novel oral, targeted agent that selectively inhibits tyrosine kinase 2 (TYK2), a Janus kinase (JAK) family member that mediates cytokine-driven immune and inflammatory signals, it has the potential to fill a gap in the treatment armamentarium for plaque psoriasis.
5. **Foscarbidopa/foslevodopa** (not yet approved by the FDA)
    a. **Indication:** Parkinson disease
    b. **Additional Information:** Novel reformulation of the gold-standard Parkinson's disease treatment (carbidopa/levodopa) delivered via a subcutaneous pump for the treatment of motor fluctuations in advanced Parkinson's disease.

6. **Lequembi™ (lecanemab) and donanemab** (not yet approved by the FDA)
    a. **Indication:** Alzheimer's disease
    b. **Additional Information:** The FDA's accelerated approval of Aduhelm™ (aducanumab) for the treatment of early Alzheimer's disease in 2021 met with controversy and uptake was curtailed by a lack of clinician support and Medicare coverage. Now, supported by landmark clinical data from a phase 3 trial, next-in-class anti-Aβ monoclonal antibody (MAb) lecanemab has been granted accelerated approval by FDA. Donanemab, and others in the class (e.g., Roche's gantenerumab), may follow suit pending the results of ongoing trials. Differentiation in the areas of adverse events (AEs), convenience and clinical and biomarker efficacy will be key determinants of future uptake.
7. **Sunlenca™ (lenacapavir)**
    a. **Indication:** HIV
    b. **Additional Information:** First-in-class, long-acting HIV1 capsid inhibitor for the treatment of multi-drug resistant (MDR) HIV in people who have been heavily treated, a patient population with unmet medical need.
8. **Mirikizumab** (not yet approved by the FDA)
    a. Indication: Crohn's disease and ulcerative colitis
    b. Additional Information: Monoclonal antibody targeting the p19 subunit of IL-23, will likely be first-in-class for ulcerative colitis and the third in the class approved for Crohn's disease.
9. **Empaveli™ (pegcetacoplan)**
    a. Indication: Geographic atrophy (GA)
    b. **Additional Information:** As one of the few drugs to have completed phase 3 trials for GA, pegcetacoplan is anticipated to be the first drug to launch for GA or 'dry late age-related macular degeneration (AMD)', which has no approved pharmacotherapy.
10. **Ritlecitinib** (not yet approved by the FDA)
    a. **Indication**: Alopecia
    b. **Additional Information:** Ritlecitinib will likely benefit from its first-in-class status, rapid onset of action and expected label for both adults and adolescents, potentially providing an effective option to stimulate hair growth in a stigmatizing disease.
11. **Sparsentan** (not yet approved by the FDA)
    a. **Indication**: Rare kidney disorders
    b. **Additional Information:** Sparsentan is a first-in-class, orally active, single molecule that functions as a high-affinity, dual-acting antagonist of both endothelin type A (ETA) and angiotensin II subtype 1 (AT1) receptors, which are associated with progression of kidney disease.
12. **Tecvayli™ (teclistamab)**
    a. **Indication:** Multiple myeloma
    b. **Additional Information:** After receiving accelerated approval from the FDA, teclistamab is the first-in-class bispecific antibody targeted to B-cell maturation antigen (BCMA) to treat multiple myeloma.
13. **Tzield™ (teplizumab)**
    a. **Indication:** Type 1 diabetes mellitus
    b. **Additional Information:** Teplizumab is the first immunotherapy to launch for T1DM and is a landmark drug given its potential ability to preserve beta cell function and delay the need for insulin treatment.
14. **Roctavian™ (valoctocogene roxaparvovec)** (not yet approved by the FDA)
    a. **Indication:** Severe hemophilia A
    b. **Additional Information:** Valoctocogene roxaparvovec is poised to be the first gene therapy to launch in the United States for severe hemophilia A. Treatment benefit is expected to last for years, reduce the number of bleeding events, minimize the need for replacement factor VIII (FVIII) and negate the use of otherwise burdensome prophylaxis treatment.

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