Aptiom drug information

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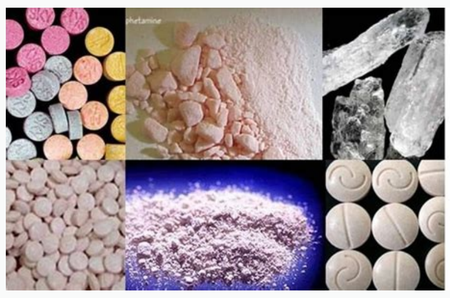

SYSTEMATIC EVOLUTION OF LIGANDS BY EXPONENTIAL ENRICHMENT

- Aptamers are typically generated by an iterative screening process of complex nucleic acid libraries (>10^{14} shapes per library) employing a process termed Systematic Evolution of Ligands by Exponential Enrichment (SELEX).
- SELEX **produces ssRNA** with specific binding target.
- This is an iterative process of **binding, partitioning, amplifying novel nucleic acids & regeneration,** the pool becomes enriched for ligands that bind the target protein with high affinity and specificity

IMPORTANT SAFETY INFORMATION AND INDICATION FOR APTIOM (eslicarbazepine acetate): It is not known if APTIOM is safe and effective in children under 4 years of age. Do not take APTIOM if you are allergic to eslicarbazepine acetate, any of the other ingredients in APTIOM, or oxcarbazepine. Suicidal behavior and ideation: Antiepileptic drugs, including APTIOM, may cause suicidal thoughts or actions in a very small number of people, about 1 in 500. Call your doctor right away if you have any of the following symptoms, especially if they are new, worse, or worry you: thoughts about suicide or dying; attempting to commit suicide; new or worse depression, anxiety, or irritability; feeling agitated or restless; panic attacks; trouble sleeping (insomnia); acting aggressive; being angry or violent; acting on dangerous impulses; an extreme increase in activity and talking (mania); or other unusual changes in behavior or mood. Allergic reactions: APTIOM may cause serious skin rash or other serious allergic reactions that may affect organs or other parts of your body like the liver or blood cells. You may or may not have a rash with these types of reactions. Call your doctor right away if you experience any of the following symptoms: swelling of the face, eyes, lips, or tongue; trouble swallowing or breathing; hives; fever, swollen glands, or sore throat that do not go away or come and go; painful sores in the mouth or around your eyes; yellowing of the skin or eyes; unusual bruising or bleeding; severe fatigue or weakness; severe muscle pain; or frequent infections or infections that do not go away. Low salt (sodium) levels in the blood: APTIOM may cause the level of sodium in your blood to be low. Symptoms may include nausea, tiredness, lack of energy, irritability, confusion, muscle weakness or muscle spasms, or more frequent or more severe seizures. Some medicines can also cause low sodium in your blood. Be sure to tell your health care provider about all the other medicines that you are taking. Nervous system problems: APTIOM may cause problems that can affect your nervous system, including dizziness, sleepiness, vision problems, trouble concentrating, and difficulties with coordination and balance. APTIOM may slow your thinking or motor skills. Do not drive or operate heavy machinery until you know how APTIOM affects you. Liver problems: APTIOM may cause problems that can affect your liver. Symptoms of liver problems include yellowing of your skin or the whites of your eyes, nausea or vomiting, loss of appetite, stomach pain, or dark urine. Most common adverse reactions: The most common side effects in patients taking APTIOM include dizziness, sleepiness, nausea, headache, double vision, vomiting, feeling tired, problems with coordination, blurred vision, and shakiness. Drug interactions: Tell your health care provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking APTIOM with certain other medicines may cause side effects or affect how well they work. Do not start or stop other medicines without talking to your health care provider. Especially tell your health care provider if you take oxcarbazepine, carbamazepine, phenobarbital, phenytoin, primidone, clobazam, omeprazole, simvastatin, rosuvastatin, or birth control medicine. Discontinuation: Do not stop taking APTIOM without first talking to your health care provider. Stopping APTIOM suddenly can cause serious problems. Pregnancy and lactation: APTIOM may cause your birth control medicine to be less effective. Talk to your health care provider about the best birth control method to use. APTIOM may harm your unborn baby. APTIOM passes into breast milk. Tell your health care provider if you are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed. You and your health care provider will decide if you should take APTIOM. If you become pregnant while taking APTIOM, talk to your health care provider about registering with the North American Antiepileptic Drug (NAAED) Pregnancy Registry. The purpose of this registry is to collect information about the safety of antiepileptic medicine during pregnancy. You can enroll in this registry by calling 1.888.233.2334. Get medical help right away if you have any of the symptoms listed above. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1.800.FDA.1088. For more information, please see the APTIOM Medication Guide and Full Prescribing Information. INDICATION: Aptiom® (eslicarbazepine acetate) is a prescription medicine to treat partial-onset seizures in patients 4 years of age and older. Pharmaceutical company Sunovion Pharmaceuticals Inc.TypeSubsidiaryIndustryPharmaceuticalsFounded1984HeadquartersMarlborough, Massachusetts, United StatesKey peopleAntony Loebel (President and CEO)ProductsLatudaAptiomKynmobiLonhala MagnairBrovanaLunestaXopenexParentSumitomo Dainippon PharmaWebsite Sunovion Pharmaceuticals Inc. (former NASDAQ: SEPR), known until October 12, 2010 as Sepracor, Inc. prior to its acquisition by Sumitomo Dainippon Pharma of Japan,[1] is a pharmaceutical company founded in 1984 by Timothy J. Barberich, Steve Matson, and Bob Bratzler. It was originally located in Princeton, New Jersey and then re-located to Marlborough, Massachusetts.[2] In addition to its headquarters location in Marlborough, Massachusetts, Sunovion has locations in London, England, Mississauga, Ontario Canada, and Fort Lee, New Jersey. Company history The company's initial focus was on the development of single isomers and active metabolites. Sepracor's products were focused on the treatment of central nervous system and respiratory disorders, under the direction of Gunnar Aberg, and John McCullough. The primary source of its revenue was the approximately $600 million annually from its Xopenex franchise of drugs. The insomnia drug Lunesta (eszopiclone) was approved by the US Food and Drug Administration (FDA) in December 2004, and launched in April 2005. On February 13, 2006, Sepracor filed a new drug application for Brovana to treat chronic obstructive pulmonary disease (COPD).[3] In September 2016, the company announced it would acquire Cynapsus Therapeutics for approximately $624 million. Through the deal, Sunovion would acquire Cynapsus' Phase III Parkinson's disease candidate drug APL-130277.[4][5] Acquisition by Dainippon Sumitomo A formal announcement of the acquisition was made on October 12, 2010, which stated that Sunovion would be an indirect, wholly owned subsidiary of Dainippon Sumitomo Pharma Co. Ltd.[1] Beneficiaries, partners, and subsidiaries Eslicarbazepine acetate In 2008, Bial agreed with Sepracor that its antiepileptic eslicarbazepine acetate (trade name Aptiom) would be produced in Sepracor's facilities and supervised by Bial.[6] References ^ a b Company press release ^ SEPR: Profile for SEPRACOR INC - Yahoo! Finance ^ "FDA Approves Sepracor, Inc.'s BROVANA(TM) (Arformoterol Tartrate) Inhalation Solution For Chronic Obstructive Pulmonary Disease". BioSpace. Retrieved 2020-02-10. ^ "Sunovion to Acquire Cynapsus for $624M - GEN News Highlights - GEN". ^ "Sunovion Pharmaceuticals to Acquire Cynapsus Therapeutics". www.businesswire.com. 2016-08-31. Retrieved 2020-02-10. ^ "Bial - caring for your health". External links Sunovion Pharmaceuticals, Inc. Retrieved from " UPDATE 11/6/2019 FDA has posted a draft document titled “Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff.” This best practices document is required under a provision of the 21st Century Cures Act. The Act includes a revision to a previous statutory requirement that generally required FDA to undertake routine safety analyses of drugs 18 months following approval or after 10,000 individuals have used the drug, whichever occurs later. Comments will be accepted on this document through the related docket, as detailed in the Federal Register Notice. Due to the changes outlined in the draft best practices document, the content on this web page will be archived when the document is finalized. What is FDA posting? This website provides summary information about ongoing and completed postmarket safety evaluations of adverse experience reports made to FDA for New Drug Applications (NDAs) and Biologics License Applications (BLAs) approved since September 27, 2007. The evaluations are done to determine if there are any new serious adverse events not previously identified during product development, known side effects reported in unusual number, or potential new safety concerns now that the products are being used in the general population. In accordance with Title IX, section 915 of the Food and Drug Administration Amendments Act of 2007 (FDAAA) which created a new section 505(r) of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 355(r)), these postmarket evaluations are performed 18 months after approval of the drug or after its use by 10,000 individuals, whichever is later. Why is FDA posting this summary information? FDA is posting this information in accordance with section 505(r) of the FDCA. This section of the statute directs FDA to improve the transparency of information about drugs and to provide patients and health care providers better access to information about drugs by developing a website with specified types of drug safety information. In response to the statutory requirement, FDA developed the Postmarket Drug Safety Information for Patients and Providers website, which has links to a wide variety of drug safety information, including this web page. What information is provided on this website? The table in each quarterly report lists the names of drug and biological products, application number, approval date, approved indication, summary of evaluation findings, actions taken, and ongoing surveillance activities. Beginning with the period from July 2012 to December 2012, drugs with an active moiety that has not been previously approved or legally marketed in the United States in any form (also known as New Molecular Entities) appear in the table and are marked as “NME.” The table also includes all biological products, including biosimilar products. Postmarket safety evaluation findings include potential new safety concerns that are first identified during the evaluation and should not be viewed as a summary of all safety issues addressed since the product's approval. A new report will be made available each quarter beginning with the period from January 2013 to March 2013. What information does FDA consider for these postmarket safety evaluations? FDA assesses several data sources including: The product's pre-approval safety profile The product's current FDA-approved label Reports made to the FDA Adverse Event Reporting System (FAERS), previously known as AERS Reports made to the Vaccine Adverse Event Reporting System (VAERS) Manufacturer-submitted periodic safety reports Medical literature Drug utilization databases Data from post-approval clinical trials and other studies, when applicable Please see the Drug and Biologics Safety Surveillance Best Practice Statement (PDF 79KB) for more information. How is the information analyzed? Beginning not later than 18 months after approval, scientists from the Office of Surveillance and Epidemiology and Office of New Drugs in the Center for Drug Evaluation and Research (CDER) jointly review the relevant data, summarize findings and, when necessary, develop a plan to further investigate potential new safety issues for products regulated by CDER. For medical products regulated by the Center for Biologics Evaluation and Research, this safety review and evaluation is conducted by scientists from CBER's Office of Biostatistics and Epidemiology and the relevant product office (Office of Blood Research and Review, Office of Vaccine Research and Review, or Office of Cellular, Tissue and Gene Therapies). FDA compiles the postmarket safety evaluations and periodically posts the summary reports on this website. For additional information about postmarket drug and biologic safety issues, including FDA Safety Communications and web postings of Potential Signals of Serious Risks Identified from the FDA Adverse Event Reporting System (FAERS), please refer to FDA's website on Postmarket Drug Safety Information for Patients and Providers or Safety and Availability (Biologics). Postmarket Drug and Biologic Safety Evaluation Summaries (previous Postmarket Drug and Biologic Safety Evaluations) Drug Safety Evaluations Completed From April 1, 2017 to June 30, 2017 Product Name: Trade (active ingredient) with Dosage form NDA/BLA Number ("NME" indicates New Molecular Entity) Approval Date Major Indications Summary of Findings from Evaluation Actions taken and Ongoing Surveillance Activities Aptensio XR (methylphenidate hydrochloride) extended-release capsules, for oral use NDA 205831 April 17, 2015 For treating attention deficit hyperactivity disorder The potential safety issue of dystonia was identified from postmarketing adverse event reports. FDA continues to evaluate adverse event reports of dystonia to determine if regulatory action is required. Aptiom (eslicarbazepine acetate) tablets, for oral use NDA 022416 (NME) November 8, 2013 For treating partial-onset seizures as monotherapy or adjunctive therapy Three potential safety issues were identified from postmarketing adverse event reports: Hematologic events Syndrome of inappropriate ntidiuretic hormone secretion (SIADH) Atrioventricular block On September 13, 2017, an efficacy supplement for Aptiom was approved and included the addition of SIADH to the existing “Warnings and Precautions” subsection describing the risk for hyponatremia, and the addition of a new “Warnings and Precautions” subsection describing the risk for hematologic adverse reactions. It was determined that no regulatory actions related to atrioventricular block are required at this time. Bexsero (Meningococcal Group B Vaccine) BLA 125546 January, 23, 2015 For active immunization to prevent invasive disease caused by Neisseria meningitidis serogroup B in individuals 10 through 25 years of age No new safety issues were identified. No regulatory actions required at this time. Corlanor (ivabradine) tablets, for oral use NDA 206143 (NME) April 15, 2015 For reducing the risk of hospitalization for worsening heart failure in patients with stable, symptomatic chronic heart failure with left ventricular ejection fraction less than or equal to 35 percent, who are in sinus rhythm with resting heart rate greater than or equal to 70 beats per minute and either are on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use No new safety issues were identified. No regulatory actions required at this time. Epiduo Forte (adapalene and benzoyl peroxide) gel, 0.3%/2.5% is for topical use NDA 207917 July 15, 2015 For the topical treatment of acne vulgaris No new safety issues were identified. No regulatory actions required at this time. Gardasil 9 (Human Papillomavirus 9-valent Vaccine, Recombinant) BLA 125508 December 10, 2014 Prevention of cervical, vulvar, vaginal, and anal cancer caused by HPV types 16 and 18, 31, 33, 45, 52, and 58 and genital warts (condyloma acuminata) caused by HPV types 6 and 11 No new safety issues were identified. No regulatory action required at this time. Injectafer (ferric carboxymaltose) injection, for intravenous use NDA 203565 July 25, 2013 An iron replacement product for treating iron deficiency anemia in adult patients: who have intolerance to oral iron or have had unsatisfactory response to oral iron; who have non-dialysis dependent chronic kidney disease No new safety issues were identified. No regulatory actions required at this time. Jevtana (cabazitaxel) injection, for intravenous use NDA 201023 (NME) June 17, 2010 For treating hormone-refractory metastatic prostate cancer The potential safety issue of tumor lysis syndrome was identified from postmarketing adverse event reports. FDA continues to evaluate adverse event reports of tumor lysis syndrome to determine if regulatory action is required. Noxafil (posaconazole) delayed-release tablets, for oral use NDA 205053 November 25, 2013 For use as a prophylaxis of invasive Aspergillus and Candida infections in patients (13 years of age and older) who are at high risk of developing these infections No new safety issues were identified. No regulatory actions required at this time. Opdivo (nivolumab), solution for injection BLA 125527, 125554 (NME) December 22, 2014 For treating: BRAF V600 wild-type unresectable or metastatic melanoma, as a single agent BRAF V600 mutation-positive unresectable or metastatic melanoma, as a single agent Unresectable or metastatic melanoma, in combination with ipilimumab Metastatic non-small cell lung cancer and progression on or after platinum based chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving Opdivo Advanced renal cell carcinoma in patients who have received prior anti-angiogenic therapy Classical Hodgkin lymphoma that has relapsed or progressed after autologous hematopoietic stem cell transplantation (HSCT) and posttransplantation brentuximab vedotin Recurrent or metastatic squamous cell carcinoma of the head and neck with disease progression on or after a platinum-based therapy Locally advanced or metastatic urothelial carcinoma who: have disease progression during or following platinum-containing chemotherapy; have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. Three potential safety issues were identified from postmarketing adverse event reports: Retinal detachment Severe vision loss Tumor lysis syndrome FDA continues to evaluate adverse event reports of retinal detachment, severe vision loss, and tumor lysis syndrome to determine if regulatory action is required. Otrexup (methotrexate) injection, for subcutaneous use only NDA 204824 October 11, 2013 For managing severe, active rheumatoid arthritis in selected adults or children with active polyarticular juvenile idiopathic arthritis, who have had insufficient therapeutic response to, or are intolerant of, an adequate trial of first-line therapy including full dose non-steroidal anti-inflammatory agents For controlling symptoms of severe, recalcitrant, disabling psoriasis that is not adequately responsive to other forms of therapy, but only when the diagnosis has been established, as by biopsy and/or after dermatologic consultation Potential device-related safety issues were identified from postmarketing adverse event reports. No regulatory action required at this time. ProAir RespiClick (albuterol sulfate) inhalation powder, for oral inhalation use NDA 205636 March 31, 2015 For treating or preventing bronchospasm in patients 4 years of age and older with reversible obstructive airway disease For preventing exercise-induced bronchospasm in patients 4 years of age and older No new safety issues were identified. No regulatory actions required at this time. Tuzistra XR (codeine polistirex and chlorpheniramine polistirex) extended-release oral suspension, CIII NDA 207768 April 30, 2015 For relief of cough symptoms associated with upper respiratory allergies or a common cold No new safety issues were identified. No regulatory actions required at this time. Velphoro (sucroferric oxyhydroxide) chewable tablets, for oral use NDA 205109 November 27, 2013 For the control of serum phosphorus levels in patients with chronic kidney disease on dialysis Two potential safety issues were identified from postmarketing adverse event reports: On August 3, 2017, a labeling supplement was approved that included the addition of information in the “Adverse Reactions; Postmarketing Experience” section of labeling pertaining to reports of tooth discoloration and rash. Zarxio (filgrastim-sndz) injection, for subcutaneous or intravenous use BLA 125553 March 6, 2015 For decreasing the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever For reducing the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia (AML) For reducing the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation For mobilizing autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis For reducing the incidence and duration of sequelae of severe neutropenia (e.g. fever, infections, orophyaryngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia No new safety issues were identified. No regulatory actions required at this time. Zortress (everolimus) tablets, for oral use NDA 021560 April 20, 2010 For the prophylaxis of organ rejection in adult patients No new safety issues were identified. No regulatory actions required at this time. Product Name: Trade (active ingredient) with Dosage form NDA/BLA Number ("NME" indicates New Molecular Entity) Approval Date Major Indications Summary of Findings from Evaluation Actions taken and Ongoing Surveillance Activities Finacea (azelaic acid) foam, 15% for topical use NDA 207071 July 29, 2015 For the topical treatment of the inflammatory papules and pustules of mild to moderate rosacea No new safety issues were identified. No regulatory actions required at this time. Humalog (insulin lispro) injection, for subcutaneous or intravenous use NDA 205747 May 26, 2015 A concentrated (200 units/ml) rapid acting human insulin analog for improving glycemic control in adults and children with diabetes mellitus No new safety issues were identified. No regulatory actions required at this time. Ibrance (palbociclib) capsules, for oral use NDA 207103 (NME) February 3, 2015 For treating hormone receptor (HR)-positive, human epidermal growth receptor 2 (HER-2)-negative advanced or metastatic breast cancer in combination with an aromatase inhibitor as initial endocrine based therapy in postmenopausal women; or fulvestrant in women with disease progression following endocrine therapy No new safety issues were identified. No regulatory actions required at this time. Prezcobix (darunavir and cobicistat) tablets, for oral use NDA 205395 January 29, 2015 For use in combination with other antiretroviral agents for treating HIV-1 infection in treatment-naïve and treatment-experienced adults with no darunavir resistance-associated substitutions No new safety issues were identified. No regulatory actions required at this time. Stiolto Respimat (tiotropium bromide and olodaterol) inhalation spray, for oral inhalation use NDA 206756 May 21, 2015 For long-term, once-daily maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease No new safety issues were identified. No regulatory actions required at this time. Triumeq (abacavir, dolutegravir, and lamivudine) tablets, for oral use NDA 205551 August 22, 2014 For treating human immunodeficiency virus (HIV-1) infection The potential safety issue of anxiety was identified from postmarketing adverse event reports. FDA continues to evaluate adverse event reports of anxiety to determine if regulatory action is required. Viberzi (eluxadoline) tablets, for oral use NDA 206940 (NME) May 27, 2015 For treating irritable bowel syndrome with diarrhea in adults The potential safety issue of hypersensitivity reactions, including anaphylaxis, was identified from postmarketing adverse event reports. FDA continues to evaluate adverse event reports of hypersensitivity reactions, including anaphylaxis, to determine if regulatory action is required. 2007-2014 reports are in the FDA Archive Previous Postmarket Drug and Biologic Safety Evaluation Summaries Related Information ResourcesForYou

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