

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AZURITY PHARMACEUTICALS, INC.,
Petitioner,

v.

HELSINN HEALTHCARE S.A.,
Patent Owner.

Case IPR2025-00948
Patent No. 9,943,515

PATENT OWNER'S CURRENT LIST OF EXHIBITS

LIST OF EXHIBITS

Exhibit No.	Description	Previously Submitted
2001	Curran, P. et al., <i>Aprepitant A Review of its Use in the Prevention of Nausea and Vomiting</i> , <i>Drugs</i> 2009: 69 (13): 1853-1878	X
2002	EMEND® (aprepitant) FDA Approval Letter, NDA 21-549, dated March 26, 2003, available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2003/21-549_Emend_Approv.pdf	X
2003	Ruhlmann, <i>Casopitant: a novel NK1-receptor antagonist in the prevention of chemotherapy-induced nausea and vomiting</i> , <i>Therapeutics and Clinical Risk Management</i> 2009:5 375-384	X
2004	Emend IV (fosaprepitant) FDA Approval Letter, NDA 22-023, dated January 25, 2008, available at https://www.accessdata.fda.gov/drugsatfda_docs/NDA/2008/022023s000_Approv.pdf	X
2005	Akynzeo (netupitant/palonosetron) FDA Approval Letter, dated October 10, 2014, available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/205718Orig1s000Approv.pdf	X
2006	Global CINV Drugs Market \$4.3 Billion by 2031, <i>ihealthcareanalyst</i> , Feb. 3, 2025, available at https://www.ihealthcareanalyst.com/global-chemotherapy-induced-nausea-vomiting-drugs-market/	X
2007	Heron Form 10-K, Feb. 27, 2025	X
2008	Azurity (Aprepitant Injectable Emulsion) FDA Tentative Approval Letter, NDA 218754, dated July 25, 2024, available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2024/218754Orig1s000TAltr.pdf	X

Exhibit No.	Description	Previously Submitted
2009	U.S. Patent No. 12,097,197 to Dubewar et al.	X
2010	IDS Statement, Application No. 18/069,204, dated June 29, 2023	X
2011	Press Release – CutisPharma Announces Acquisition of Silvergate Pharmaceuticals, Name Change to Azurity Pharmaceuticals, June 12, 2019, 6:00 ET	X
2012	Press Release – Silvergate Pharmaceuticals Release: FDA Approves XATMEP, The First and Only Ready-To-Use Methotrexate Oral Solution, April 26, 2017	X
2013	GLIADEL [®] WAFER label	X
2014	Press Release - Azurity Pharmaceuticals Acquires Slayback Pharma, Sept. 27. 2023, available at https://azurity.com/azurity-pharmaceuticals-acquires-slayback-pharma/	X
2015	U.S. Patent Application Publication No. 2024/0156829 A1	X
2016	EMEND [®] label, March 2003	X
2017	An Efficacy and Safety Study of Oral Netupitant and Palonosetron for the Prevention of Nausea and Vomiting, last updated Nov. 26, 2014, available at https://clinicaltrials.gov/study/NCT01339260	X
2018	A Safety Study of Oral Netupitant and Palonosetron for the Prevention of Nausea and Vomiting, last updated Nov. 17, 2014, available at https://clinicaltrials.gov/study/NCT01376297	X
2019	An Efficacy and Safety Study of Oral and Intravenous Palonosetron for the Prevention of Nausea and Vomiting, last updated Sept. 22, 2021, available at https://clinicaltrials.gov/study/NCT01363479	X

Exhibit No.	Description	Previously Submitted
2020	FDA Approves Akynzeo for Injection, FDA Approves Intravenous Formulation of Akynzeo (fosnetupitant/palonosetron) for Chemotherapy-Induced Nausea and Vomiting, available at https://www.drugs.com/newdrugs/fda-approves-intravenous-formulation-akynzeo-fosnetupitant-palonosetron-chemotherapy-induced-nausea-4726.html	X
2021	Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, available at https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=002&Appl_No=210493&Appl_type=N	X
2022	Netupitant and Palonosetron Hydrochloride in Preventing Chemotherapy Induced Nausea and Vomiting in Patients With Cancer Undergoing BEAM Conditioning Regimen Before Stem Cell Transplant, last updated Jul 12, 2021, available at https://clinicaltrials.gov/study/NCT03097588	X
2023	PK/ PD Study of Netupitant and Palonosetron in Pediatric Patients for Prevention of Chemotherapy-induced Nausea and Vomiting (CINV), last updated Jun 25, 2024, available at https://clinicaltrials.gov/study/NCT03204279	X
2024	A Study to Assess the Safety and the Efficacy of IV Fosnetupitant/ Palonosetron (260 mg/ 0.25 mg) Combination Compared to Oral Netupitant/ Palonosetron (300 mg/ 0.5 mg) Combination for the Prevention of CINV in AC Chemotherapy in Women With Breast Cancer, last updated Jun 1, 2020, available at https://clinicaltrials.gov/study/NCT03403712	X
2025	Safety and Antiemetic Efficacy of Akynzeo Plus Dexamethasone During Radiotherapy and Concomitant Weekly Cisplatin, last updated Dec. 14, 2021, available at https://clinicaltrials.gov/study/NCT03668639	X

Exhibit No.	Description	Previously Submitted
2026	Oral Akynzeo® Vs Standard of Care in Preventing CINV in High-risk MEC Patients (MyRisk) (CINV), last updated Dec. 4, 2024, available at https://clinicaltrials.gov/study/NCT04817189	X
2027	A Clinical Trial to Assess Safety and Pharmacokinetics of Fosnetupitant 235mg and Metabolites in Healthy Volunteers, last updated May 4, 2025, available at https://clinicaltrials.gov/study/NCT06840769	X
2028	Prevention of Breakthrough CINV in Patients Receiving Moderately or Highly Emetogenic Chemotherapy, last updated Oct. 10, 2023, available at https://clinicaltrials.gov/study/NCT06065722	X
2029	Study With IV NEPA (Fosnetupitant/ Palonosetron) for the Prevention of Chemotherapy-induced Nausea and Vomiting in Paediatric Cancer Patients Undergoing Highly Emetogenic Chemotherapy (HEC), last updated Jul 28, 2025, available at https://clinicaltrials.gov/study/NCT06904235	X
2030	An Efficacy and Safety Study of Intravenous Palonosetron Administered as an Infusion and as a Bolus for the Prevention of Nausea and Vomiting, last update Jun 20, 2018, available at https://clinicaltrials.gov/study/NCT02557035	X
2031	A Safety Study of Intravenous Pro-Netupitant and Palonosetron Combination for the Prevention of Nausea and Vomiting, last updated Jun 20, 2018, available at https://clinicaltrials.gov/study/NCT02517021	X
2032	U.S. Patent No. 5,202,333 to Berger et al.	X
2033	Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, available at https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&Appl_No=210493&Appl_type=N	X

Exhibit No.	Description	Previously Submitted
2034	Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, available at https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&Appl_No=205718&Appl_type=N	X
2035	AKYNZEO [®] label	X
2036	Navari, R.M. Pharmacological Management of Chemotherapy-Induced Nausea and Vomiting. <i>Drugs</i> 69, 515–533 (2009). https://doi.org/10.2165/00003495-200969050-00002 (Published March 2009)	X
2037	Ettinger et al., Antiemesis Clinical Practice Guidelines in Oncology, <i>Journal of the National Comprehensive Cancer Network</i> , 7(5): 572-595 (May 2009)	X
2038	Reserved	
2039	Navari et al, “Olanzapine for the Prevention of Chemotherapy-Induced Nausea and Vomiting”, <i>New England Journal of Medicine</i> , 375(2), 134-142, 2016, https://doi.org/10.1056/NEJMoa1515725	X
2040	Reserved	
2041	Reserved	
2042	MARINOL [®] (Dronabinol) label	X
2043	CESAMET [™] (Nabilone) label	X
2044	Navari CV	X
2045	Albert, J.S. et al., "Structural analysis and optimization of NK1 receptor antagonists through modulation of atropisomer interconversion properties." <i>J. Med. Chem.</i> 2004, 47, 519-529.	X
2046	Veenstra S.J. et al., "Studies on the active conformation of NK1 antagonist CGP 49823. Part 1. Synthesis of conformationally restricted analogs," <i>Bioorganic & Medicinal Chemistry Letters</i> , 7(3): 347-350 (1997)	X

Exhibit No.	Description	Previously Submitted
2047	Goldstein D.J. et al., "Lanepitant, an NK-1 antagonist, in migraine prevention," <i>Cephalalgia</i> , 2001 Mar; 21(2):102-6	X
2048	George D.T. et al. "Neurokinin 1 Receptor Antagonism as a possible therapy for alcoholism," <i>Science</i> 319: 1536-1539 (2008)	X
2049	Fujii, T. et al., "Pharmacological profile of a high affinity dipeptide NK1 receptor antagonist, FK888," <i>Br. J. Pharmacol.</i> 107:785-789 (1992)	X
2050	Diemunsch, Pierre, and Laurent Grélot, "Potential of substance P antagonists as antiemetics," <i>Drugs</i> 60(3): 533-546 (2000)	X
2051	Diemunsch, P. et al., "Neurokinin-1 receptor antagonists in the prevention of postoperative nausea and vomiting." <i>British Journal of Anaesthesia</i> , 103(1): 7-13 (2009)	X
2052	Rosso, M. et al. "The NK-1 receptor is expressed in human primary gastric and colon adenocarcinomas and is involved in the antitumor action of L-733,060 and the mitogenic action of substance P on human gastrointestinal cancer cell lines." <i>Tumor Biol.</i> 29(4): 245-254 (2008)	X
2053	Cascieri, M. et al. "Characterization of the binding and activity of a high affinity, pseudoirreversible morpholino tachykinin NK1 receptor antagonist." <i>European Journal of Pharmacology</i> 325(2-3): 253-26 (1997)	X
2054	Sindrup, S. et al., "The NK1-receptor antagonist TKA731 in painful diabetic neuropathy: a randomised, controlled trial." <i>European Journal of Pain</i> 10(6): 567-571 (2006)	X
2055	Vendruscolo, F. et al. "Evaluation of the anxiolytic-like effect of NKP608, a NK1-receptor antagonist, in two rat strains that differ in anxiety-related behaviors." <i>Psychopharmacology</i> 170(3): 287-293 (2003)	X

Exhibit No.	Description	Previously Submitted
2056	Saito, R. et al. "Anti-emetic effects of a novel NK-1 receptor antagonist HSP-117 in ferrets." <i>Neuroscience letters</i> 254(3): 169-172 (1998)	X
2057	Ebner, K. et al., "Tachykinin receptors as therapeutic targets in stress-related disorders," <i>Current Pharmaceutical Design</i> 15(14): 1647-1674 (2009)	X
2058	Shishido, Y. et al. "Discovery and stereoselective synthesis of the novel isochroman neurokinin-1 receptor antagonist 'CJ-17,493'." <i>Bioorganic & Medicinal Chemistry</i> 16(15): 7193-7205 (2008)	X
2059	De la Puente-Redondo, V. et al. "The neurokinin-1 antagonist activity of maropitant, an antiemetic drug for dogs, in a gerbil model." <i>Journal of Veterinary Pharmacology and Therapeutics</i> 30(4): 281-287 (2007)	X
2060	Rudd, J et al., "Inhibition of emesis by tachykinin NK1 receptor antagonists in <i>Suncus murinus</i> (house musk shrew)." <i>European Journal of Pharmacology</i> 366(2-3): 243-252 (1999)	X
2061	Quartara, Laura and Altamura, Maria, "Tachykinin receptors antagonists: from research to clinic." <i>Current Drug Targets</i> 7(8): 975-992 (2006)	X
2062	Emonds-Alt, Xavier et al. "SSR240600 [(R)-2-(1-{2-[4-{2-[3, 5-Bis (trifluoromethyl) phenyl] acetyl}-2-(3, 4-dichlorophenyl)-2-morpholinyl] ethyl}-4-piperidinyl)-2-methylpropanamide], a Centrally Active Nonpeptide Antagonist of the Tachykinin Neurokinin-1 Receptor: I. Biochemical and Pharmacological Characterization." <i>The Journal of Pharmacology and Experimental Therapeutics</i> 303(3): 1171-1179 (2002)	X
2063	Shue, H. et al. "Cyclic urea derivatives as potent NK1 selective antagonists." <i>Bioorganic & Medicinal Chemistry Letters</i> 15(17): 3896-3899 (2005)	X

Exhibit No.	Description	Previously Submitted
2064	Araya, I. et al. "Process development and large-scale synthesis of NK1 antagonist." <i>Chemical and Pharmaceutical Bulletin</i> 56(2): 176-180 (2008)	X
2065	Hesse, C. et al. "Kinetics and dynamics of the peripheral neurokinin-1 receptor antagonist SLV317 in healthy individuals." <i>British Journal of Clinical Pharmacology</i> 61(4): 414-419 (2006)	X
2066	Megens AA, Ashton D, Vermeire JC, Vermote PC, Hens KA, Hillen LC, Fransen JF, Mahieu M, Heylen L, Leysen JE, Jurzak MR, Janssens F. Pharmacological profile of (2R-trans)-4-[1-[3,5-bis(trifluoromethyl)benzoyl]-2-(phenylmethyl)-4-piperidiny]-N-(2,6-dimethylphenyl)-1-acetamide (S)-Hydroxybutanedioate (R116301), an orally and centrally active neurokinin-1 receptor antagonist. <i>J Pharmacol Exp Ther.</i> 302(2):696-709 (2002 Aug)	X
2067	Reserved	
2068	Reserved	
2069	IPR2025-00948: Declaration of Rudolph Modesto Navari, M.D., Ph.D, F.A.C.P.	X
2070	Reserved	
2071	Declaration of Melanie Rupert in Support of Motion for Pro Hac Vice	X
2072	Declaration of Justin T. Fleischacker in Support of Motion for Pro Hac Vice	X
2073	Schmoll, H.J. et al., <i>Comparison of an aprepitant regimen with a multiple-day ondansetron regimen, both with dexamethasone, for antiemetic efficacy in high-dose cisplatin treatment</i> , <i>Annals of Oncology</i> 17:1000-1006 (2006)	
2074	<i>Emesis, Vomiting</i> , Black's Medical Dictionary (41 st ed. 2005)	

Exhibit No.	Description	Previously Submitted
2075	Bloechl-Daum, B. et al., <i>Delayed Nausea and Vomiting Continue to Reduce Patients' Quality of Life After Highly and Moderately Emetogenic Chemotherapy Despite Antiemetic Treatment</i> , J. Clin. Oncol. 24:4472-4478 (2006)	
2076	Guidance for Industry, E9 Statistical Principles for Clinical Trials (Sept. 1998)	
2077	Press Release – GSK provides update on regulatory filings for Zunrisa/Rezonic, September 27, 2009	
2078	Hamik, A. and Peroutka, S., <i>Differential interactions of traditional and novel antiemetics with dopamine D₂ and 5-hydroxytryptamine₃ receptors</i> , Cancer Chemother Pharmacol 24:307-310 (1989)	
2079	Ison, P. and Peroutka, S., <i>Neurotransmitter Receptor Binding Studies Predict Antiemetic Efficacy and Side Effects</i> , Cancer Treatment Reports Vol. 70, No. 5, 637-641 (May 1986)	
2080	January - March 2018 Potential Signals of Serious Risks/New Safety Information Identified from the FDA Adverse Event Reporting System (FAERS)	
2081	Jordan, K. et al., <i>Chemotherapy-induced nausea and vomiting: current and new standards in the antiemetic prophylaxis and treatment</i> , European Journal of Cancer, 41 (2005) 199-205	
2082	O'Brien, M.E.R. et al., <i>The role of metoclopramide in acute and delayed chemotherapy induced emesis: a randomised double blind trial</i> , Br. J. Cancer, 60 (1989) 759-763	
2083	Peroutka, S., <i>Combination Antiemetics</i> , Cancer Treatment Reports, Vol. 66, No. 6, (June 1982) 1449	
2084	Peroutka, S., <i>Chemotherapeutic agents do not interact with neurotransmitter receptors</i> , Cancer Chemother Pharmacol 19:131-132 (1987)	

Exhibit No.	Description	Previously Submitted
2085	Guidance for Industry, Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products (May 1998)	
2086	Deposition transcript of Stephen J. Peroutka, taken on January 13, 2026	
2087	Eric Roeland, MD, FASCO, FAAHPM Curriculum Vitae	
2088	RESERVED	
2089	RESERVED	
2090	IPR2025-00948 - Declaration of Eric Roeland, MD, FASCO, FAAHPM	
2091	RESERVED	
2092	Peroutka, S., <i>Neurogenic Inflammation and Migraine: Implications for Therapeutics</i> , 5 Molecular Interventions 3:304-311 (Oct. 2005)	
2093	COMPAZINE [®] (prochlorperazine) label	
2094	PHENERGAN [®] (promethazine) label	
2095	Arpornwirat, W., M.D. et al., <i>Phase 2 Trial Results With the Novel Neurokinin-1 Receptor Antagonist Casopitant in Combination With Ondansetron and Dexamethasone for the Prevention of Chemotherapy-Induced Nausea and Vomiting in Cancer Patients Receiving Moderately Emetogenic Chemotherapy</i> , Cancer: 5807-5816 (Dec. 15, 2009)	
2096	MacCoss, M. and Baillie, T.A., <i>Organic Chemistry in Drug Discovery</i> , Science 303:1810-1813 (Mar. 19, 2004)	
2097	REGFAN [®] (metoclopramide) label	
2098	ZYPREXA [®] (olanzapine) label	
2099	NEURONTIN [®] (gabapentin) label	

Exhibit No.	Description	Previously Submitted
2100	Park, Y. et al., <i>Nausea and vomiting in an evolving anticancer treatment landscape: long-delayed and emetogenic antibody-drug conjugates</i> , <i>Future Oncology</i> , Vol. 21, No. 10, 1261-1272 (2025)	
2101	Stahis, M. et al., <i>Inhibition of substance P-mediated responses to NG108-15 cells by netupitant and palonosetron exhibit synergistic effects</i> , <i>Eur. J. of Pharmacology</i> 689 (2012) 25-30	
2102	DOXIL [®] (doxorubicin) label	
2103	de Boer-Dennert, M., <i>Patient perceptions of the side-effects of chemotherapy: the influence of 5HT3 antagonists</i> , <i>British Journal of Cancer</i> 76(8) 1055-1061 (1997)	

Dated: February 25, 2026

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that I caused to be served on the counsel identified below a true and correct copy of the foregoing Patent Owner's Current List of Exhibits by electronic means on February 25, 2026:

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