
Platform
Therapeutics™

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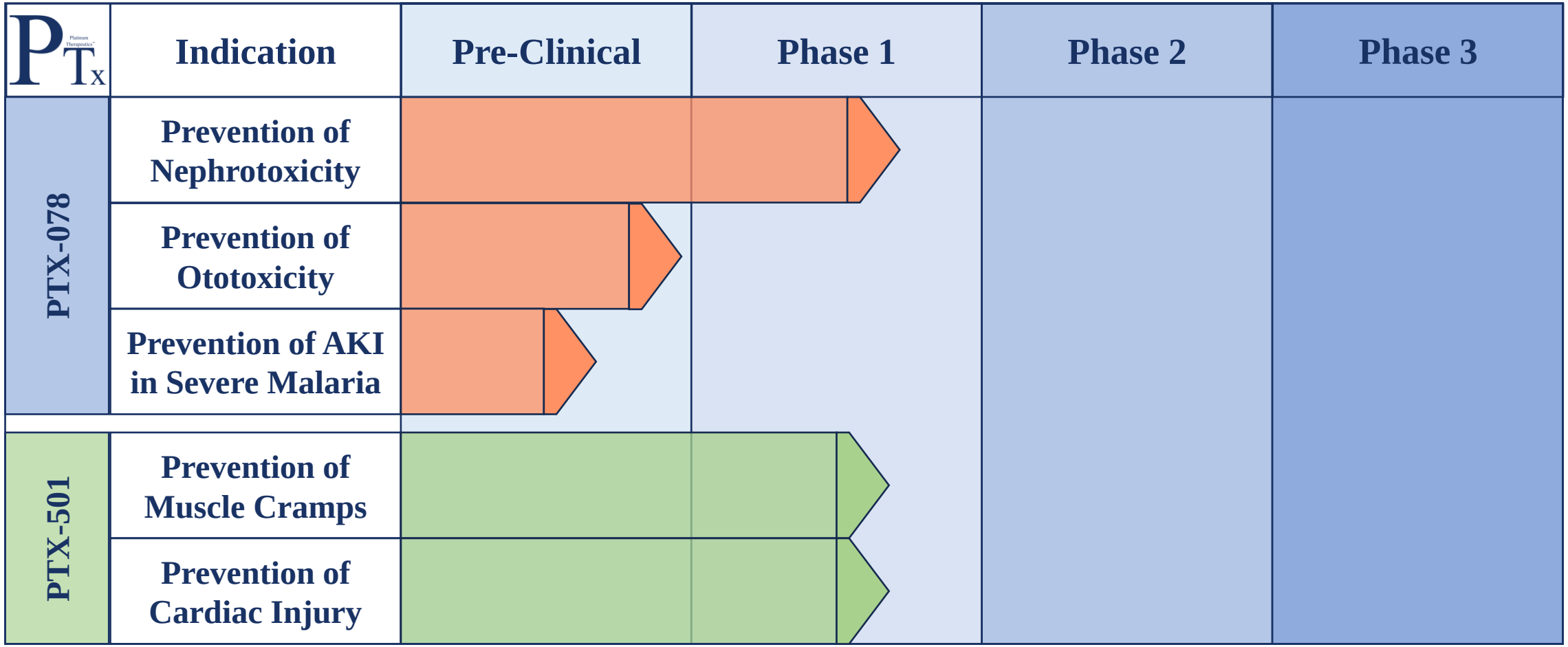
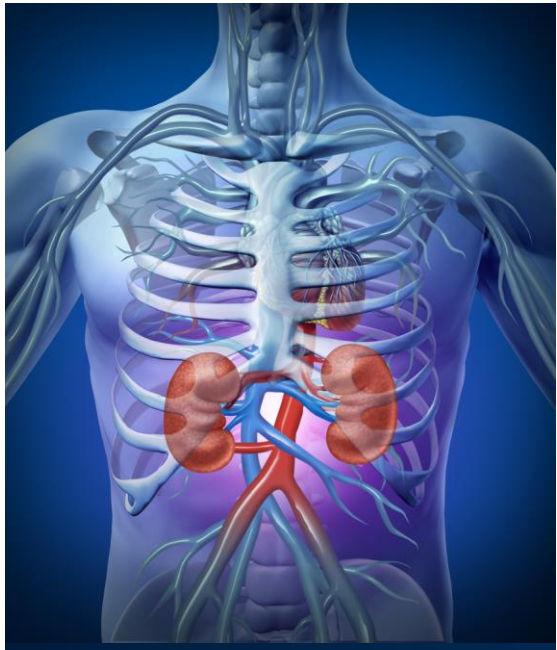
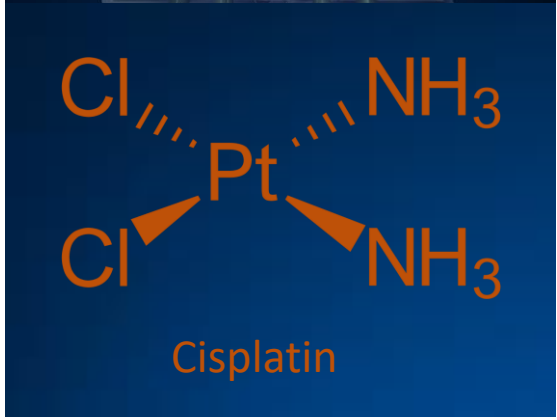
PTX Pipeline



Summary

- Patients with cancer oftentimes undergo chemotherapy with platinum-based drugs such as **cisplatin**, one of the most commonly used chemotherapy agents.
- Oncologists have major concerns about **toxicity** when treating patients with cisplatin. They monitor the patient for signs of nephrotoxicity (kidney injury) which is the primary cause of decreasing the dose and duration of treatment, **and thus potentially decreasing its effectiveness**.
- PTX-078 is designed to **prevent nephrotoxicity** in patients undergoing platinum-based chemotherapy and may allow for an increased dose and longer duration of treatment.
- The market opportunity for our first product is $2.8 billion in the United States. The market opportunity for our follow-on product, PTX-501, is $486 million.





The Technology

Toxicity of Platinum-based Chemo

- Cisplatin induced nephrotoxicity is:
  - Dose related and cumulative
  - Severe and may include acute renal failure
  - More severe and detrimental in lung cancer patients.[1]
- Geriatric patients and patients with baseline renal impairment may be more susceptible to nephrotoxicity.
- Literature places the prevalence of hearing loss at 40-60% and hearing impairment at 100 % in high-dose pediatric patients. [2]

78
Pt
Platinum
195.08

2
8
18
32
17
1

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use CISPLATIN INJECTION safely and effectively. See full prescribing information for CISPLATIN INJECTION.

CISPLATIN for injection, for intravenous use
Initial U.S. Approval: 1978

WARNING: NEPHROTOXICITY, PERIPHERAL NEUROPATHY, NAUSEA AND VOMITING, and MYELOSUPPRESSION
See full prescribing information for complete boxed warning.

- **Nephrotoxicity: cisplatin for injection can cause severe renal toxicity, including acute renal failure. Ensure adequate hydration. Consider dose reductions or alternative treatments in patients with renal impairment. (2.1, 5.1)**
- **Peripheral Neuropathy: cisplatin for injection can cause dose-related peripheral neuropathy. (5.2)**
- **Nausea and Vomiting: cisplatin for injection can cause severe nausea and vomiting. Premedicate with antiemetics. (2.1, 5.3)**
- **Myelosuppression: cisplatin for injection can cause severe myelosuppression with fatalities due to infections. Monitor blood counts and interrupt therapy accordingly. (5.4)**

----------INDICATIONS AND USAGE----------
Cisplatin for injection is a platinum-based drug indicated for the treatment of:
- Advanced testicular cancer (1.1)
- Advanced ovarian cancer (1.2)
- Advanced bladder cancer (1.3)

----------DOSAGE AND ADMINISTRATION----------
- Administer pre-treatment hydration and pre- and post-treatment antiemetics. (2.1)
- Cisplatin for injection has been administered intravenously at:
  - Advanced testicular cancer: 20 mg/m^2 daily for 5 days per cycle (2.2)
  - Advanced ovarian cancer: 75 mg/m^2 to 100 mg/m^2 per cycle once every 3 to 4 weeks (2.3)
  - Advanced bladder cancer: 50 mg/m^2 to 70 mg/m^2 intravenously per cycle once every 3 to 4 weeks (2.4)

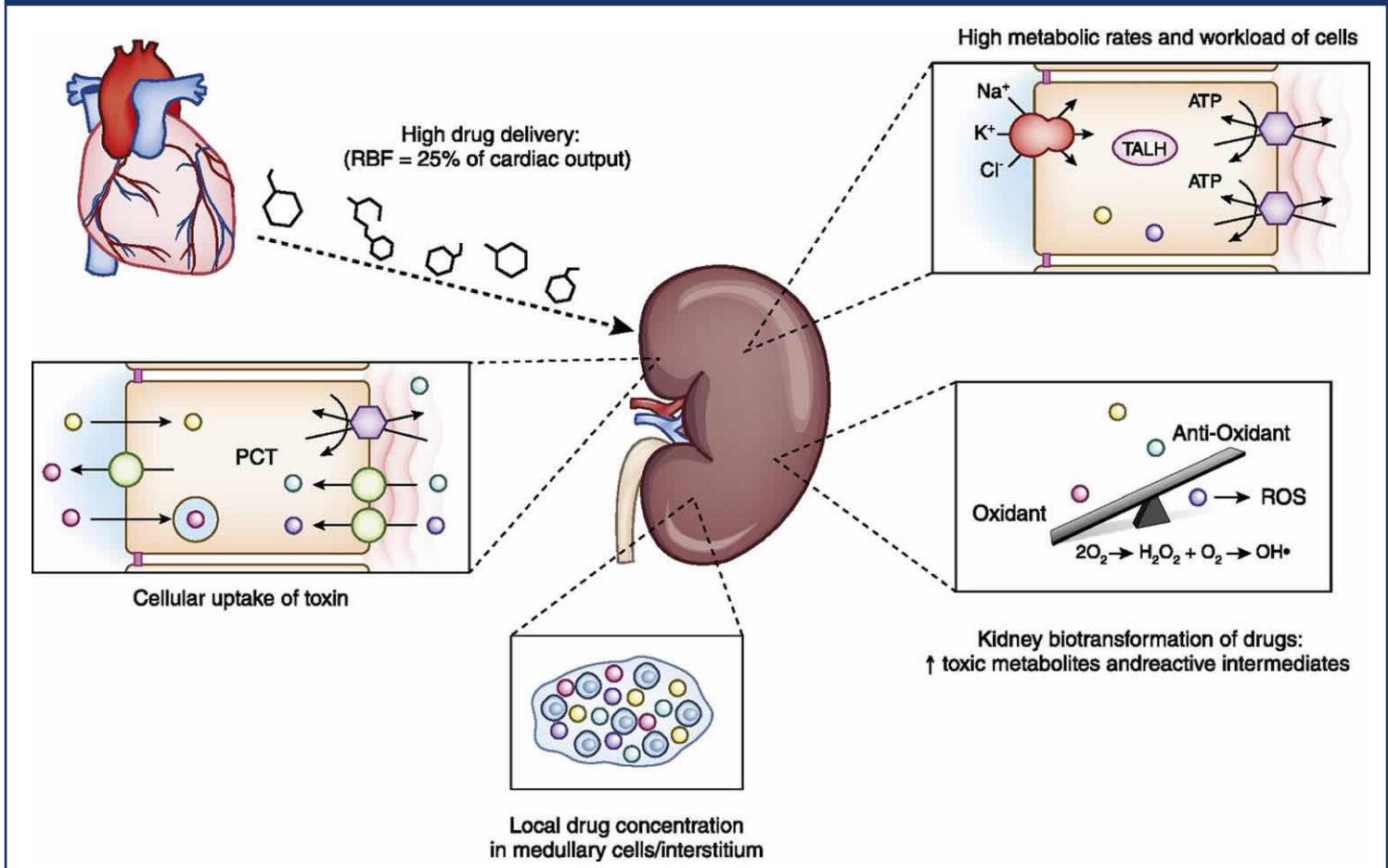
Refer to current treatment guidelines for specific dosing information.

Sources:
1. Cisplatin package insert.
2. Kopelman J, Budnick AS, Sessions RB, Kramer MB, Wong GY. Ototoxicity of high dose cisplatin by bolus administration in patients with advanced cancers and normal hearing. Laryngoscope. 1988 Aug;98(8 Pt 1 858 64.

Nephrotoxicity

- The kidney filters and reclaims many important molecules such as: glucose, amino acids, and electrolytes.
- Kidney tubules filter nephrotoxins, but some are retained.
- These retained molecules build up in tubular cells and cause nephrotoxicity.
- Impairment of renal function is a clinical problem in 20–35% of patients who receive a cisplatin-containing regimen. [1]
- PTX-078 temporarily allows nephrotoxins to be eliminated and protects the kidney.

Nephrotoxicity is caused by many classes of drugs

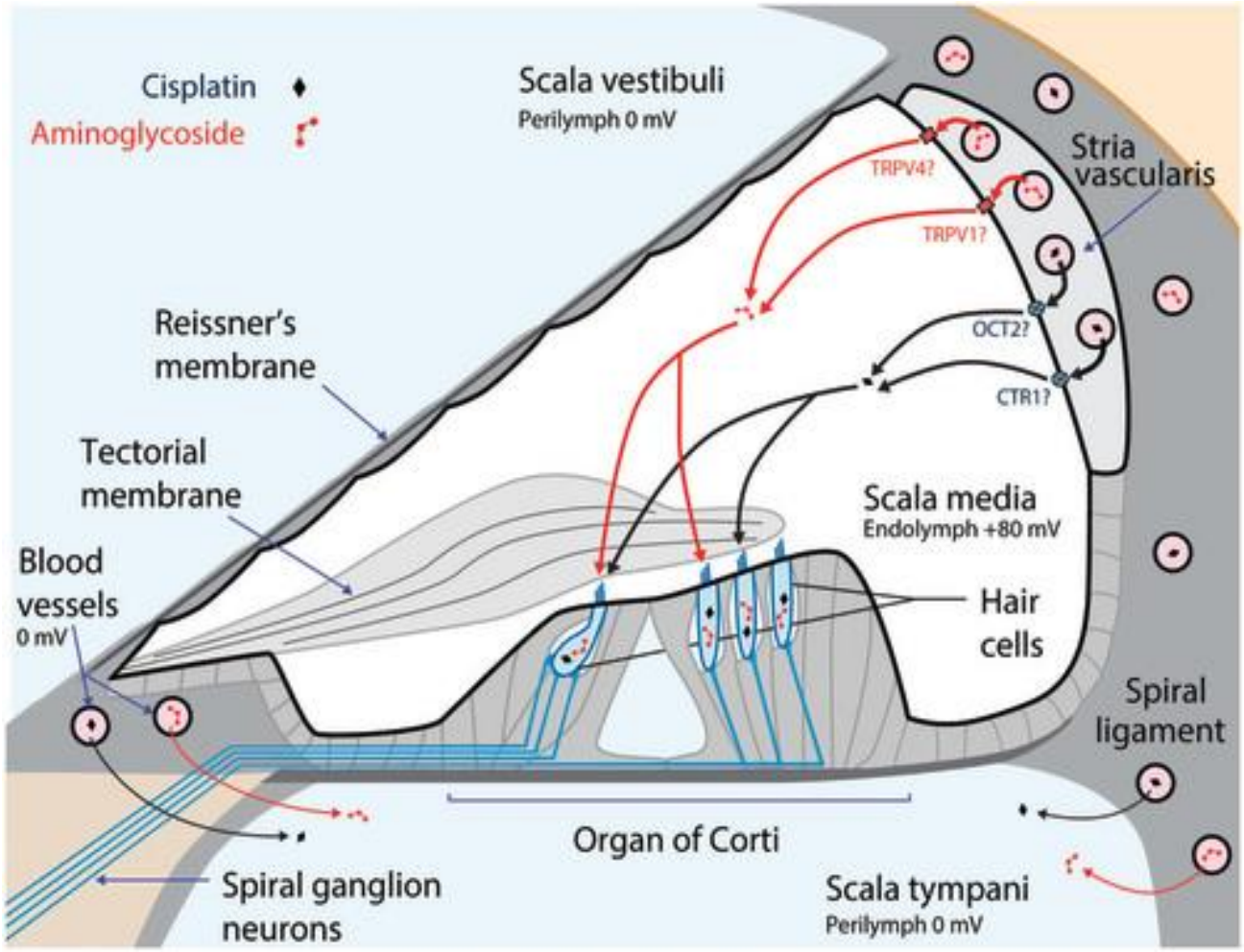


Source: https://healthjade.net/nephrotoxicity/

1. dos Santos NA, Carvalho Rodrigues MA, Martins NM, et al. Cisplatin-induced nephrotoxicity and targets of nephroprotection: an update. Arch Toxicol. 2012 Aug;86(8):1233-50.

Ototoxicity – Hearing Loss

- Certain transporters allow access of molecules into the inner ear for normal function.
- Ototoxins are also allowed access to the inner ear.
- Platinum causes increased reactive oxygen species, which lead to cell death, hearing loss and kidney failure.
- Any product that minimizes or eliminates this concern will be used in every case.
- PTX-078 is designed to protect the inner ear and allow for proper dosing and duration of treatment.
- The kidney tubular cells and inner ear share ion channels are similar in architecture.



The Market

Market Assessment

Selected cancers only, current cisplatin use only

Patient	Cases / 100k	Number of Cases	Cases Indicated for Chemo	Cases Using Chemo	Cases Using Platinum	Cases Using Cisplatin	Total Average Number of Cycles[1]	Total Cisplatin Cycles	Addressable Market ($4,175/cycle)	Physician Input Use	Corresponding PTX-078 Sales[2]
Lung, NSCLC	68.8 *(Total Lung)*	205,539 *(89.2% NSCLC)*	153,514 *(74.7%)*	86,695 *(56.5%)*	60,300 (69.6%)	29,725 *(49.3%)*	6.3	187,598	$783,223,001	93,799 *(40-60%)*	$391,611,501
Lung, SCLC	68.8 *(Total Lung)*	24,806 *(10.8% SCLC)*	24,806 *(100.0%)*[3]	16,703 *(67.3%)*	15,412 *(92.3%)*	3,671 *(23.8%)*	4.8	16,945	$70,746,678	8,473 *(40-60%)*	$35,373,339
Ovarian	14.2	24,019	22,000 *(91.3%)*	10,930 *(49.7%)*	9,408 *(86.1%)*	1,566 *(16.6%)*	4.3	6,746	$28,164,487	4,048 *(50-70%)*	$16,898,692
Breast	151.6	256,427	---	104,991 *(40.9%)*	9,133 *(8.7%)*	512 *(5.6%)*	8	4,097	$17,105,267	2,049 *(40-60%)*	$8,552,634
Bladder	24.4	81,692	20,423 *(25.0%)*	9,305 *(45.6%)*	7,097 *(76.3%)*	3,057 *(43.1%)*	4.8	14,622	$61,045,381	7,311 *(40-60%)*	$30,522,690
Testicular	5.7	9,443	---	2,774 *(29.4%)*	2,490 *(89.7%)*	2,419 *(97.1%)*	3.1	7,495	$31,289,635	6,370 *(85%)*	$26,596,190
Pediatric	6.8[4]	5,519	---	---	1,038 *(18.8%)*[4]	648 *(62.4%)*	4	2,591	$10,815,440	2,331 *(90%)*	$9,733,896
Total[5]		607,445	220,743	231,398	104,877	41,598		240,093	$1,002,389,889	124,381	$519,288,942

[1] Total average cycles across first and second line;
[2] High-level estimates based upon physician primary research inputs;
[3] Chemotherapy can be utilized at all stages;
[4] Summed across pediatric cancers (brain/CNS, non-Hodgkin lymphoma, Hodgkin lymphoma, osteosarcoma, Wilms tumor);
[5] Sums may not equal total due to rounding.

Payers find this budget impact easily acceptable given **Neulasta's** nearly $4 billion peak annual sales

Market Assessment

	Number of Chemotherapy Cycles *(cisplatin and carboplatin only)*	Price / Cycle	Market
Patient Populations Analyzed [1] *(Bladder, Breast, Colon, Lung, Ovarian, Testicular, Pediatric Cancers representing 47.5% of all cases)*			
Cisplatin cycles	240,093	$4,175	$1,002,389,889
Carboplatin cycles [20% of total (368,949) converted to cisplatin]	73,799	$4,175	$308,110,825
Sub Total	313,883	$4,175	$1,310,463,139
All other Patient Populations *(All other cancers representing 52.5% of all cases)*			
Cisplatin cycles	265,366	$4,175	$1,107,904,614
Carboplatin cycles [20% of total (368,949) converted to cisplatin]	81,548	$4,175	$340,462,680
Sub Total	346,914	$4,175	$1,448,367,294
Total	660,797	$4,175	$2,758,830,434

[1] Extensive market research was conducted for the following patient populations: bladder, breast, colon, lung, ovarian, testicular, and certain pediatric cancers, which represent about 47.5% of all cases. See detailed market research report for analysis.

Summary of Market Assessment

- Quotes from Oncologists
  - "Toxicity is a serious thing, especially with Cisplatin. If it [PTX-078] works, I will use it."
  - "Cisplatin is stronger but it's toxic. If I could use this successfully, **I could move patients to Cisplatin**."
  - "Cisplatin is considered more active than carboplatin. This is an extremely important product."
  - "If the patients have vision loss, it's especially important to prevent hearing loss because that's all they have."
- Summary from Interviews with Payers
  - Payers readily acknowledged platinum-based toxicity is a prominent issue.
  - Clearly stated that **PTX-078 would need to be covered, even at elevated prices.**
    - "We have to cover it since it's a supporting therapy in oncology."
    - "It definitely will be covered. We don't really have a choice."
    - "Yes. It's related to cancer. We cover all of those drugs."
- Payers find the price of PTX-078 easily acceptable given Neulasta's nearly $4 billion peak annual sales.

Founding Team

James Wilkie, Founder & CEO

James Wilkie has 38 years of experience in the life sciences industry developing both drugs and devices. Jim was the co-founder and CEO of Lowell Therapeutics, which was acquired by AcelRx Pharmaceuticals in 2022. He joined La Jolla Pharmaceutical Co. in 2014 as the VP of New Enterprise Development responsible for identifying New Drug Candidates and he spun out Lowell Therapeutics. Prior to joining LJPC, Jim served as COO of Pluromed, Inc., until the sale of the company in 2012 to Sanofi. He joined Pluromed in 2005 as VP of Operations and led the development team to commercialize two successful products in the U.S. and Europe, where he was responsible for the overall operation. Prior to his experience at Pluromed, he held various positions of increasing responsibility at MedChem Products, Inc., including Director of Engineering for 3 sites. Upon the sale of MedChem to C. R. Bard, he spun-off certain technology and co-founded Surgical Sealants, Inc. He holds 4 issued patents and several pending applications. Jim received his B.S. in Engineering from the University of Massachusetts in 1985.

Lakhmir (Mink) Chawla, MD, Founder & Chairman

Dr. Chawla led the development and FDA approval of Giapreza, an ICU drug with 14 issued patents and $35 million revenue. He was Professor of Medicine at George Washington University where he held dual appointments in the Department of Anesthesiology and Critical Care Medicine. Dr. Chawla was the Chief of the Division of Intensive Care Medicine at the Washington D.C. Veterans Affairs Medical Center. He received the International Vicenza Award for Critical Care Nephrology in June 2015, which recognizes individuals who have made seminal clinical research advancements that have significantly improved the care of critically ill patients with AKI and have been adopted worldwide. Dr. Chawla was selected as the recipient of the Vicenza Award for his contributions to the development of the renal angina model, the development and standardization of the furosemide stress test, the link between AKI and chronic kidney disease (CKD), and the use of angiotensin II in the treatment of high-output shock. He is an internationally renowned expert in the field of AKI and is an active investigator in the fields of inflammation and AKI, AKI biomarkers, AKI risk prediction, chronic kidney disease caused by AKI and AKI therapeutics. Dr. Chawla is the author of over 100 peer-reviewed publications and was previously an Associate Editor for the Clinical Journal of the American Society of Nephrology.

Founding Team

Arthur Atkinson, MD, Founder (1938-2024)

Dr. Atkinson received his A.B. degree in Chemistry from Harvard College in 1959 and his M.D. from Cornell University Medical College in 1963. While at Northwestern, he and his colleagues set up the first laboratory devoted to drug monitoring, conducted the first clinical investigations to develop the acetylated metabolite of procainamide as an antiarrhythmic drug, carried out the first PK studies with stable isotope-labeled drugs, and completed basic research that elucidated the physiologic basis of some multicompartmental models of drug distribution. In 1994, Dr. Atkinson was appointed Corporate VP for Clinical Development and Medical Affairs at Upjohn. Following the Upjohn-Pharmacia merger, he joined the Center for Drug Development Science at Georgetown University as an Adjunct Professor of Pharmacology. From 1975 to 1979, Dr. Atkinson served as a member of the Pharmacology/Toxicology Program Committee of the National Institute of General Medical Sciences (NIGMS), and from 1984 to 1986, chaired the Pharmacological Sciences Program Committee for that institute. In 1997, he returned to NIH as a Special Expert Consultant in Clinical Pharmacology for NIGMS. He was appointed Senior Advisor in Clinical Pharmacology to the Director of the NIH Clinical Center where he directed the ClinPRAT postdoctoral training program and the Clinical Center course on *Principles of Clinical Pharmacology*. Dr. Atkinson is a Master of the American College of Physicians (MACP) and has been President of the Chicago Society of Internal Medicine, President of the American Board of Clinical Pharmacology, and President of the American Society for Clinical Pharmacology and Therapeutics. He serves as an Emeritus Associate Editor of *Clinical Pharmacology and Therapeutics* and Emeritus Editor of *Translational and Clinical Pharmacology*. He has served as an editor for all four editions of the *Principles of Clinical Pharmacology* textbook, which in the fourth edition was re-named *Atkinson's Principles of Clinical Pharmacology.* He received the Harry Gold Award from ASPET, the Oscar Hunter Award from ASCPT, and the Award in Excellence from the PhRMA Foundation.

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