

# Safe Harbor Statement



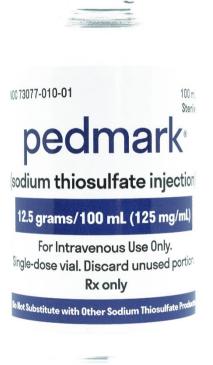
Except for historical information described in this press release, all other statements are forward-looking. Words such as "believe," "anticipate," "plan," "expect," "estimate," "intend," "may," "will," or the negative of those terms, and similar expressions, are intended to identify forward-looking statements. These forward-looking statements include statements about our business strategy, timeline and other goals, plans and prospects, including our commercialization plans respecting PEDMARK®, the market opportunity for and market impact of PEDMARK®, its potential impact on patients and anticipated benefits associated with its use, and potential access to further funding after the date of this release. Forward-looking statements are subject to certain risks and uncertainties inherent in the Company's business that could cause actual results to vary, including the risks and uncertainties that regulatory and guideline developments may change, scientific data and/or manufacturing capabilities may not be sufficient to meet regulatory standards or receipt of required regulatory clearances or approvals, clinical results may not be replicated in actual patient settings, unforeseen global instability, including political instability, or instability from an outbreak of pandemic or contagious disease, such as the novel coronavirus (COVID-19), or surrounding the duration and severity of an outbreak, protection offered by the Company's patents and patent applications may be challenged, invalidated or circumvented by its competitors, the available market for the Company's products will not be as large as expected, the Company's products will not be able to penetrate one or more targeted markets, revenues will not be sufficient to fund further development and clinical studies, our ability to obtain necessary capital when needed on acceptable terms or at all, the Company may not meet its future capital requirements in different countries and municipalities, and other risks detailed from time to time in the Company's filings with the Securities and Exchange Commission including its Annual Report on Form 10-K for the year ended December 31, 2023. Fennec disclaims any obligation to update these forward-looking statements except as required by law.

For a more detailed discussion of related risk factors, please refer to our public filings available at <a href="https://www.sec.gov">www.sec.gov</a> and <a href="https://www.sec.gov">www.sec.gov<

# Fennec Pharmaceuticals is a Commercial Stage Biotechnology Company Dedicated to Improving the Lives of Children with Cancer

- **PEDMARK**® is FDA-approved to reduce the risk of ototoxicity or hearing loss associated with cisplatin in pediatric patients 1 month of age and older with localized, non-metastatic solid tumors.
  - Unique formulation of sodium thiosulfate specifically developed in pediatrics
  - U.S. commercial launch October 2022
- 7 years U.S. market exclusivity with Orphan Drug Designation
- Orange Book Patents provide protection until 2039
- In Europe:
  - EU approval received June 2023; UK approval received October 2023
  - 10 YEARS E.U. exclusivity with Pediatric-use Marketing Authorization (PUMA)
  - Entered into exclusive licensing agreement with Norgine to commercialize PEDMARQSI in Europe, Australia and New Zealand





US packaging represented

# PEDMARK® Registrational Trials Met Their Endpoints



### **Registrational Trials Design**

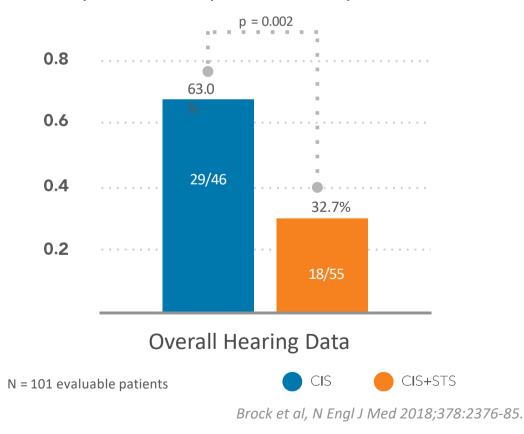
SIOPEL 6: randomized, controlled, open-label study of 114 patients aged 1 month to 18 years receiving cisplatin-based chemotherapy for standard risk hepatoblastoma

COG ACCL0431: randomized, controlled, openlabel study of 125 patients aged 1 to 18 years w/ solid tumors receiving a chemotherapy regimen for any stage disease that included a cumulative cisplatin dose of ≥200 mg/m²

### **Primary Endpoint: Hearing Loss**

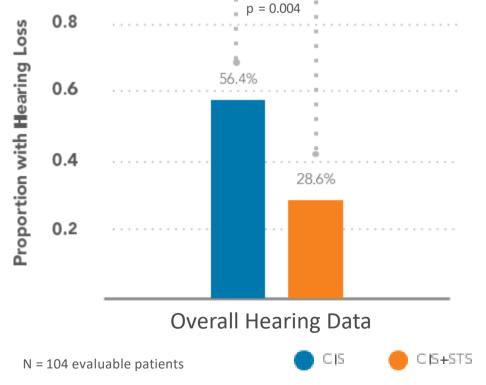
PEDMARK reduced the relative risk of hearing loss

by 48% compared with cisplatin alone\*



PEDMARK reduced the relative risk of hearing loss





Freyer et al, www.thelancet.com/oncology Vol 18 January 2017

### **Manageable Safety Profile**

- The most common adverse reactions (≥25% with difference between arms of >5% compared to cisplatin alone) in SIOPEL6 are:
  - Vomiting
  - Nausea
  - Decreased hemoglobin
  - Hypernatremia
- The most common adverse reaction (≥25% with difference between arms of >5% compared to cisplatin alone) in COG ACCL0431 is:
  - Hypokalemia

<sup>\*</sup>A total of 109 children were randomly assigned to receive cisplatin plus sodium thiosulfate (n=57) or cisplatin alone (n=52) and could be evaluated. The absolute hearing threshold was assessed in 101 children. PEDMARK's FDA-approved label included patients without data that were lost to follow up and assumed to have hearing loss.

<sup>\*\*</sup>A total of 125 children were randomly assigned to receive either sodium thiosulfate (n=61) or observation (n=64). Of these, 104 participants were assessable for the primary endpoint. PEDMARK's FDA-approved label included patients without data that were lost to follow up and assumed to have hearing loss. The on-label reduction in relative risk of hearing loss with PEDMARK is 25% compared with cisplatin alone.





# **Cisplatin | Penicillin of Chemotherapy**

- Interferes with DNA replication killing fast proliferating cells
- Administered as intravenous infusion in normal saline
  - For treatment of solid and hematological malignancies
  - Relatively short half-life
- First licensed in 1979
  - Introduced in pediatric patients in 1980s
  - It is on the WHO's List of Essential Medicines
  - High cure rates achieved in pediatric patients, in contrast to adults

# Common Childhood Cancers Treated with Cisplatin

- Brain and CNS cancers
- Osteosarcoma

Neuroblastoma

Germ cell tumors

- Hepatoblastoma
- Retinoblastoma

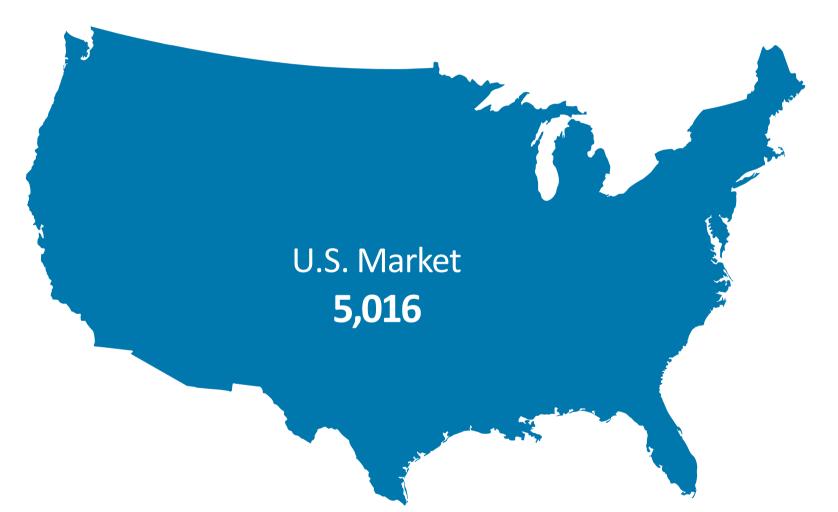
Treatment plan depends on the individual cancer diagnosis, stage of disease and patient age

Platinum cancer drugs. Available at cisplatin.org Accessed September 7, 2022. Robertson J, et al. Bull World Health Organ. 2016 Oct 1; 94(10): 735–742. Ward et al. CA Cancer J Clin. 2014;64:83-103.









~30% 1,462 Metastatic~70% 3,554 Localized, non-metastatic



~30% 1,710 Metastatic~70% 4,215 Localized, non-metastatic

\*Sources: <a href="http://accis.iarc.fr/results/2003/pdfs/summaryincidencetables.pdf">http://accis.iarc.fr/results/2003/pdfs/summaryincidencetables.pdf</a> Accessed Feb 2022; Ward, E CA CANCER J CLIN 2014;64:83-103

Localized vs metastatic breakdown based on Qualitative Market Research Study Completed February 2018







## **Common Clinical Presentation of Hearing Loss**

- High frequency (≥4 kHz) sensorineural hearing loss<sup>1,2</sup>
  - Bilateral (both ears)
  - Progressive
  - Irreversible
  - Can progress to include lower frequencies (<4 kHz)<sup>3</sup>
- Can be accompanied by tinnitus<sup>3</sup>
- Prolonged retention of platinum may cause hearing loss progression after completion of therapy<sup>4</sup>
- Hearing aids may be necessary in up to 40%; and cochlear implants in an additional percentage of children affected<sup>3</sup>

# **Risk Factors for Ototoxicity**<sup>1,2</sup>

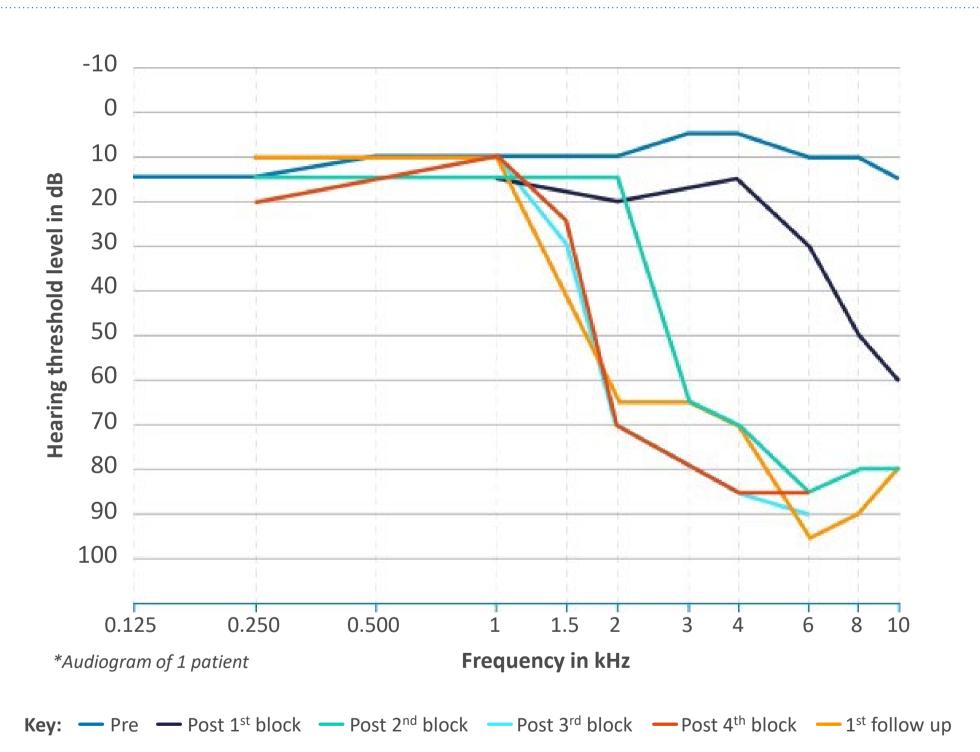
- Younger age (<5 years of age)</li>
- Cranial irradiation
- Total dose and duration of platinum agent
- Exposure to other ototoxic medications
- Pre-existing renal insufficiency
- Pre-exposure to therapies that impair hearing ability
- Genetic factors

Hearing loss that is serious enough for hearing aid use has been independently associated with declines in cognition and educational performance<sup>5</sup>

1. Waissbluth S et al. Int J Pediatr Otorhinolaryngol. 2018;111:174-179. 2. Paken J et al. J Toxicol. 2016;2016:1809394. 3. Langer T et al. Trends in Pharmacological Sciences. 2013;34:458-469. 4. Sprauten M. J. Clin Oncol. 2012;30:300-307. 5. Schreiber et al., Neuro Oncol, 2014;16(8):1129-36.







- Ototoxicity is a cisplatin dose-limiting toxicity<sup>1</sup> meaning that efficacy of chemotherapy could be compromised due to ototoxicity management
- Effects can be seen as soon as the second or third dose of cisplatin
- Survivors are at risk of hearing deterioration years after completion of therapy<sup>2</sup>

Langer T et al. Trends in Pharmacological Sciences. 2013;34:458-469. 2. Bertolini P et al, J Pediatric Hem Onc 2004;26:649-655.

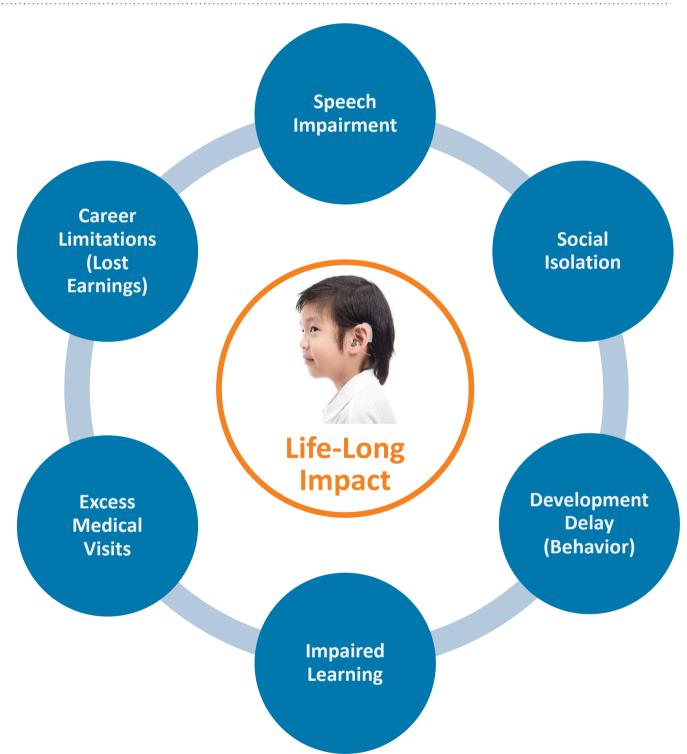
Audiogram indicates how loud a sound must be to hear it at a given frequency.

# Clinical Manifestations

# **Effects on growth and development**

- Certain consonants (f/th/p/k/h/t) are inaudible, compromising speech recognition and comprehension in young children<sup>1</sup>
- High frequency hearing loss affects recognition of plurals such as /s/ in 'ducks' and /z/ in 'girls', resulting in delayed language development<sup>3</sup>
- Speech perception in background noise is hindered, resulting in poorer school performance (e.g., literacy)<sup>1,4,5</sup>
- Impaired perception of music and ambient noises, resulting in a poorer quality of life<sup>1</sup>
- Delayed neurocognitive and psychosocial development<sup>1</sup>

Hearing loss is associated with a lower IQ, phonetic decoding and reading comprehension<sup>6</sup>

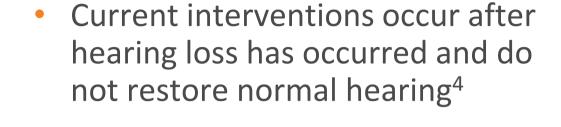


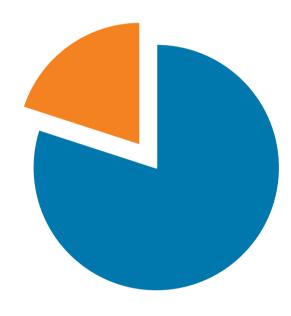
Langer T et al. Trends in Pharmacological Sciences. 2013;34:458-469.
 Bertolini P et al, J Pediatric Hem Onc 2004;26:649-655.
 Brock PR et al. J Clin Oncol 2010;30:2408-2417.
 Gurney JG et al. Pediatrics. 2007;e1229-e1236.
 Crandell CC. Ear & Hearing. 1993; 14:210-217.
 Hennegan, K, Silber A, Dehipawala S, Chithran K, Lockhart D. Poster PIH67. ISPOR Annual Meeting 2020.



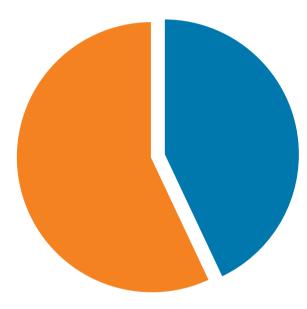


• The overall 5-year survival rate for children with localized, non-metastatic disease is 85% or greater, making the permanent and progressive impact of ototoxicity an important consideration<sup>1</sup>, yet audiological follow up, today, is inconsistent

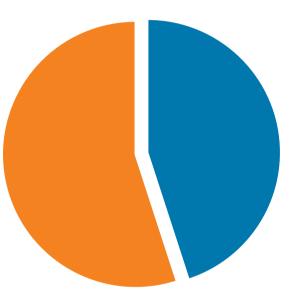




Nearly 1 in 5 children (18%) considered at-risk for hearing loss do not have hearing tests during follow-up<sup>2</sup>



More than half (57%) children do not have full audiological monitoring before, during, and after treatment<sup>2</sup>



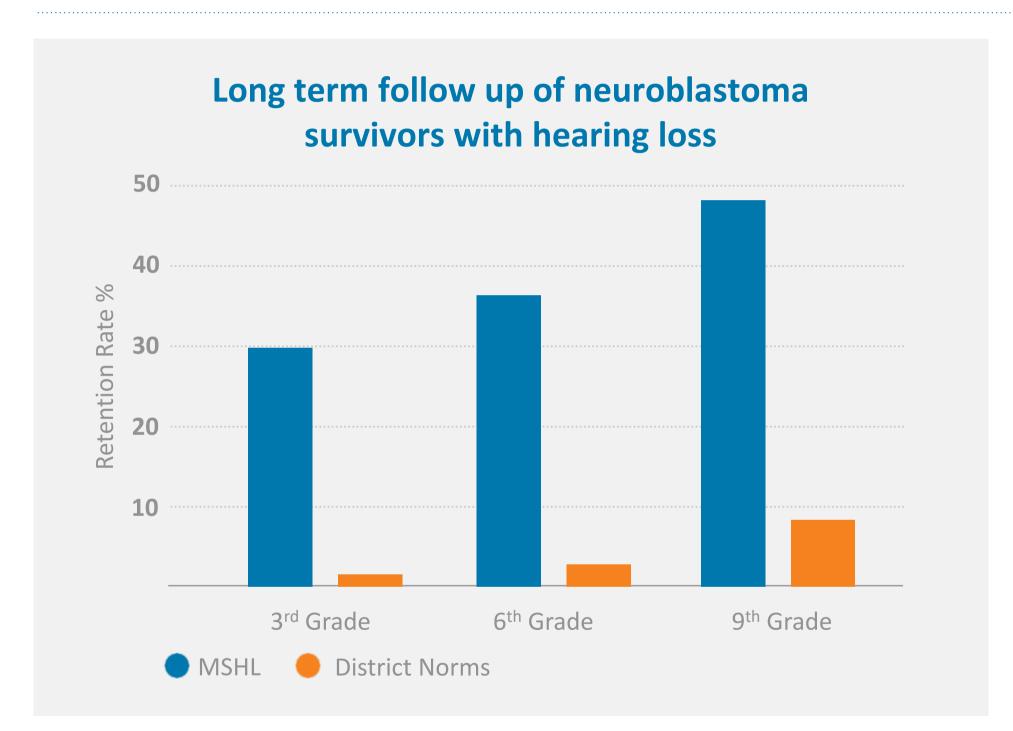
More than half (55%) of children with hearing loss have not been documented to require hearing aids<sup>3</sup>

60% [and up to 90%] of children develop irreversible ototoxicity resulting in a devastating and life-long impact<sup>1</sup>

1. ACS Key Statistics for Childhood Cancer <a href="https://www.cancer.org/cancer/cancer-in-children/key-statistics.html">https://www.cancer.org/cancer/cancer-in-children/key-statistics.html</a>. 2. Clemens E, van den Heuvel-Eibrink MM, Mulder RL, et al.; Lancet Oncol. 2019;20(1):e29-e41. 3. Hennegan, K, Silber A, Dehipawala S, Chithran K, Lockhart D. Poster PIH67. ISPOR Annual Meeting 2020. 4. Landier W.; Cancer. June 2016; Vol. 122,No.11: 1647-1658. 5. Langer T, Zehnhoff-Dinnesen A; Trends in Pharmacological Sciences. August 2013, Vol. 34, No. 8: 458-469.

# Ototoxicity Can Have a Devastating Impact





- High risk for being held back a grade (37% vs. 3%)<sup>1</sup>
- Twice the rate of parents reported learning problems with reading, math, attention and need for special education<sup>2</sup>
- Poorer child-reported school functioning

Even minimal hearing loss is damaging, resulting in compromised learning and language development<sup>1</sup>

1. Bess et al., Ear and Hearing, 1998, 19:339-54. 2. Gurney et al., Pediatrics, 2007 120 (5):229-36 Minimum sensorineural hearing loss (MSHL).





# Intervention occurs after hearing loss has been detected

### **Hearing Aids<sup>1</sup>**

- Do not block out background noise
- Unable to separate speech and noise in loud environments
- Don't allow distant sounds to be heard
- Generally replaced every 3-5 years<sup>2</sup>

# Personal Frequency Modulation (FM Classroom Amplification)

- Patients with hearing loss as a result of cisplatin therapy are more likely to need hearing loss amplification technology e.g., extended bandwidth hearing aids<sup>1</sup>
- There is no data suggesting improvement in speech recognition with this technology<sup>3</sup>

### Cochlear Implants<sup>1</sup>

- A surgically implanted neuro-prosthetic device to provide a modified sense of sound for moderate to profound sensorineural hearing loss
- Could be unilateral or bilateral
- Lifelong commitment

## **Speech Rehabilitation<sup>3</sup>**

- Speech reading and counseling on compensatory communication strategies are needed
- Counseling should include family members including parents and siblings

1. Landier W. Cancer. 2016;122:1647-1658.

2. <a href="https://www.starkey.com/blog/2014/02/5-common-questions-about-hearing-aids accessed Feb 18th 2020">https://www.starkey.com/blog/2014/02/5-common-questions-about-hearing-aids accessed Feb 18th 2020</a>.

3. Paken et al, Journal of Toxicology 2016, 1809394 | Image: <a href="https://pubs.asha.org/">https://pubs.asha.org/</a>

# Commercial Strategy



PEDMARK® is the
First and Only FDA- and
EMA-Approved Agent to
Lower the Risk of
Cisplatin-Induced
Hearing Loss in Children
with Localized Solid
Tumors



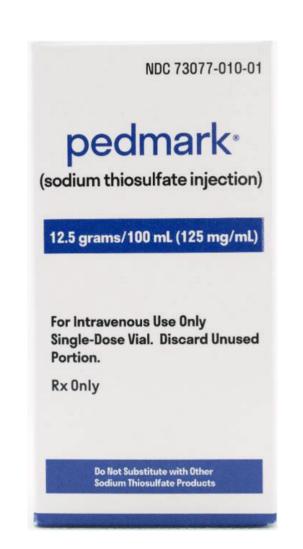
 Establish PEDMARK® as the necessary complementary agent when prescribing a cisplatin- based therapy for a child with a localized solid tumor

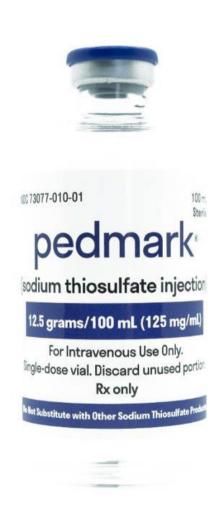
- Minimize barriers to access and rapid responses to questions
- Establish Fennec as an optimal partner in pediatric oncology

# PEDMARK® Value Proposition

- Only FDA- and EMA-approved treatment for CIO across pediatric solid tumors, based on two Phase 3 clinical studies
  - PEDMARK® and PEDMARQSI™ are indicated to prevent the risk of ototoxicity associated with cisplatin in pediatric patients 1 month of age and older with localized, non metastatic solid tumors
- Clear benefit with ~50% reduction in hearing loss
- Only commercial pharmaceutical company dedicated to CIO with no branded competitor in development
- Unique formulation developed for children with differentiated excipient profile with mild-to-moderate and manageable side effect profile
- Rapid infusion time
- NCCN AYA guidelines adoption Category 2A







# NCCN Guidelines Category 2A – Significant Opportunity in Adolescents And Young Adults (AYA)



- The Adolescent And Young Adult (AYA) oncology patient Is defined as an individual aged 15–39 years of age at the time of initial cancer diagnosis
- PEDMARK Label Does NOT Have Age Restrictions
- Treatment Related Issues
  - AYA patients should be offered enrollment in open clinical trials for their specific disease when available and appropriate and supportive care should follow wellestablished guidelines such as those available at www.NCCN.org
- Toxicities
  - Ototoxicity Consider sodium thiosulfate to prevent the risk of ototoxicity associated with cisplatin in pediatric patients with localized, non-metastatic solid tumors.

Note: All recommendations are category 2A unless otherwise indicated





### There is only one PEDMARK®



NCCN Guidelines for Adolescent and Young Adult Oncology recommends sodium thiosulfate (PEDMARK) as a preventative treatment option to reduce CIO in pediatric patients with localized, non-metastatic solid tumors.<sup>1</sup>

NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

PEDMARK is the first and only FDA-approved STS formulation for cisplatin-induced ototoxicity<sup>2</sup>

Source: NCCN Guidelines V3.2023 – AYA Oncology, 09.01.2023 https://www.nccn.org/guidelines/guidelines-detail?category=4&id=1412.

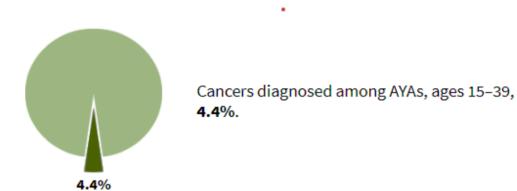
# **AYA Opportunity**

Adolescent and young adult (AYA) cancer patients, those who are diagnosed with cancer for the first time at the age of 15–39 years, are recognized as a distinct population within the oncology community for spontaneous use due to the unique challenges they face throughout their disease trajectory.



#### At a Glance

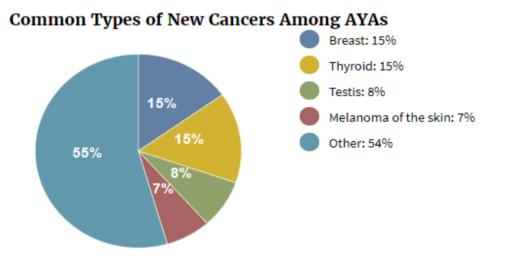
Based on estimates of new cancer cases in 2023, 4.4% of all new cases will occur among ages 15 to 39. 85.8% of AYAs diagnosed with cancer will survive their cancer for 5 years after diagnosis.





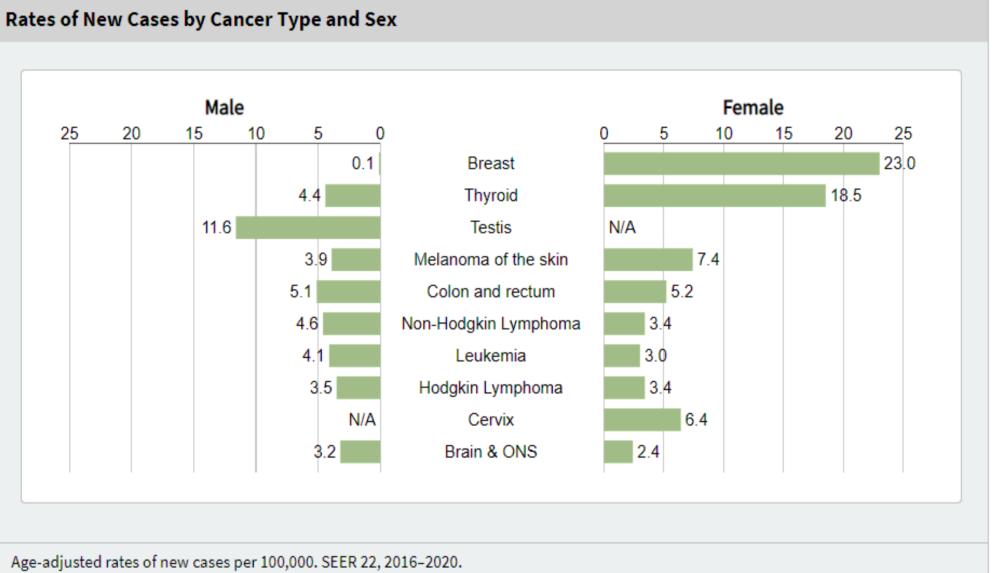
#### New Cancer Cases, 2023

Estimated New Cancers Among AYAs in the U.S. in 2023	85,980
% of All New Cancer Cases at Any Age	4.4%



Distribution based on age-adjusted rates of new cases. SEER 22, 2016–2020.

https://seer.cancer.gov/statfacts/html/aya.html



https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(18)30858-1/fulltext

Childhood, adolescent, and young adult (CAYA) cancer survivors treated with platinum-based drugs, head or brain radiotherapy, or both have an increased risk of ototoxicity (hearing loss, tinnitus, or both).

PEDMARK® is FDA-approved to reduce the risk of ototoxicity or hearing loss associated with cisplatin in pediatric patients 1 month of age and older with localized, non-metastatic solid tumors.

# Key Activities





### **Direct Promotion**

- Digital materials
- Digital MD speaker bureau to engage pediatric oncologists, audiologists, nursing and pharmacists



# **Aligned Commercial & Medical Infrastructure**

- Sales team originally focused on target pediatric facilities
- Expanded team with record of success in community oncology sales (October)



# **Commercial Partnerships**

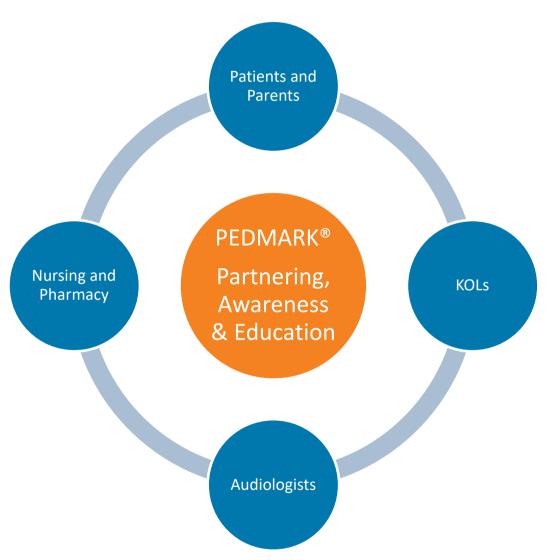
- Several contracts recently signed with group purchasing organizations
- Specialty pharmacy offering, home infusions, white bag delivery, and direct billing



### **Access & Patient Support**

- 3PL and distribution network
- Patient access services HUB
- Strong support from advocacy groups

# **Ongoing Partnerships**

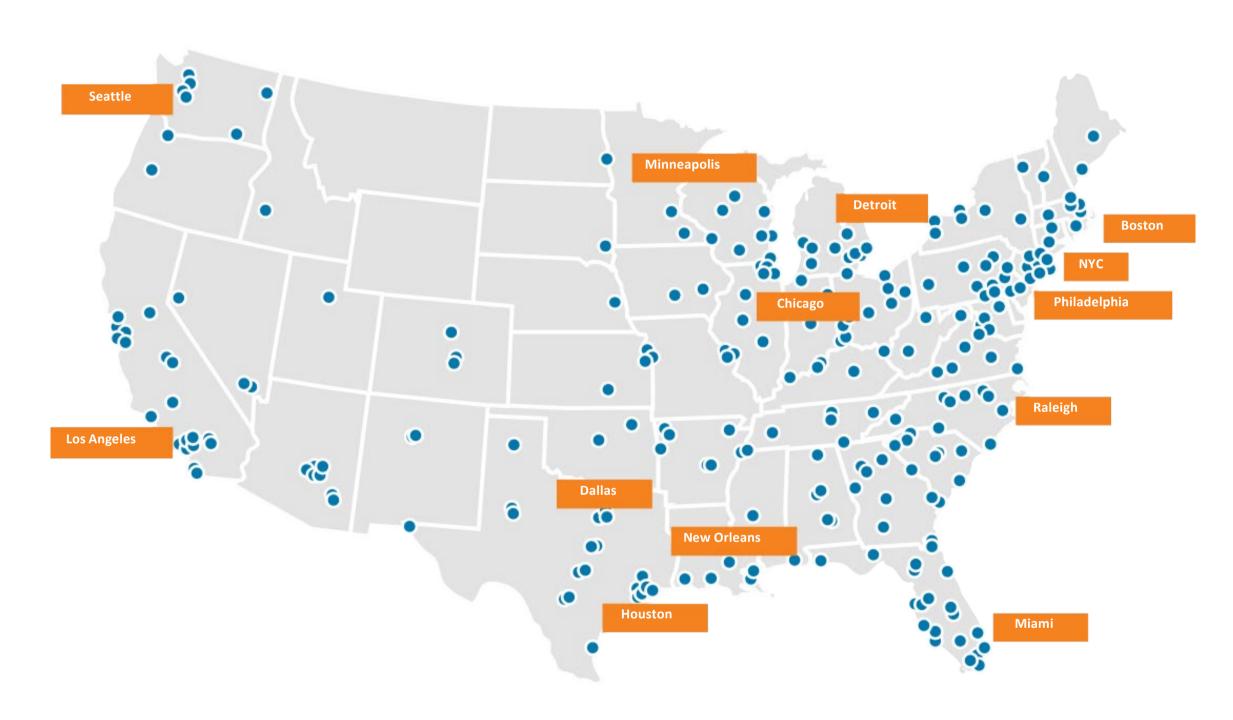


# U.S. Pediatric Oncology Landscape



# **Institutions**

- ~500 target pediatric hospital centers including COG, NCI and NCCN institutions\*
- ~80% of cisplatin use driven by key centers ~200 institutions



\*COG: Children's Oncology Group; NCI: National Cancer Institute; NCCN: National Comprehensive Cancer Network

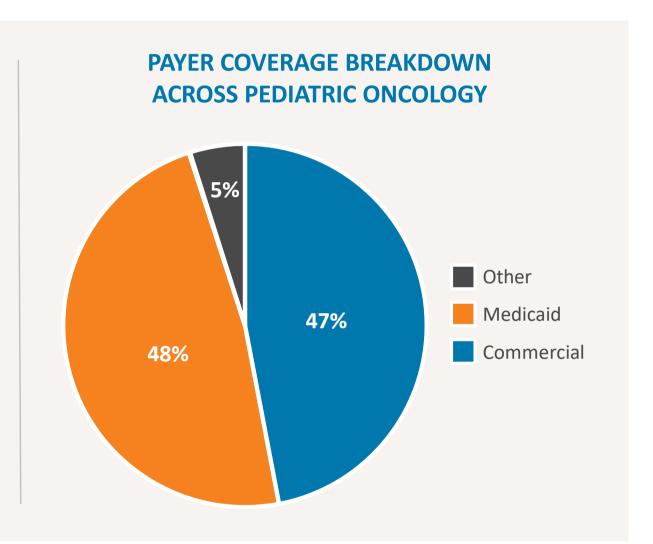




### **Payors**

According to HCUP 2016\*
pediatric oncology patients are:

- 48% covered by commercial insurance
- 50% covered by Medicaid



## Setting

50% patients treated inpatient, ~25% coded to inpatient

- Outpatient: buy and bill with a J-code
- Inpatient: some patients will be coded to a DRG

<sup>\*</sup> HCUP: The Healthcare Cost and Utilization Project, <a href="https://www.hcup-us.ahrq.gov/">https://www.hcup-us.ahrq.gov/</a>

# FENNEC HEARS | Education, Access & Reimbursement Support





# A single source program for patients needing financial and product access support

### **Financial Support**

- \$0 copay savings eligibility for patients with commercial or private insurance
- Copay assistance through independent charities for eligible Medicaid recipients
- The Fennec Patient Assistance Program for eligible patients without insurance

### **Patient & Product Support**

- Fennec HEARS dedicated care coordinators available to:
  - Answer insurance questions about coverage for PEDMARK
  - Provide you with tips and resources for managing your child's treatment

# Commercial Success With Institutions Via Multiple Stakeholders

**Ongoing Partnerships** 







APHON Dinners
Programs Completed
or Planned

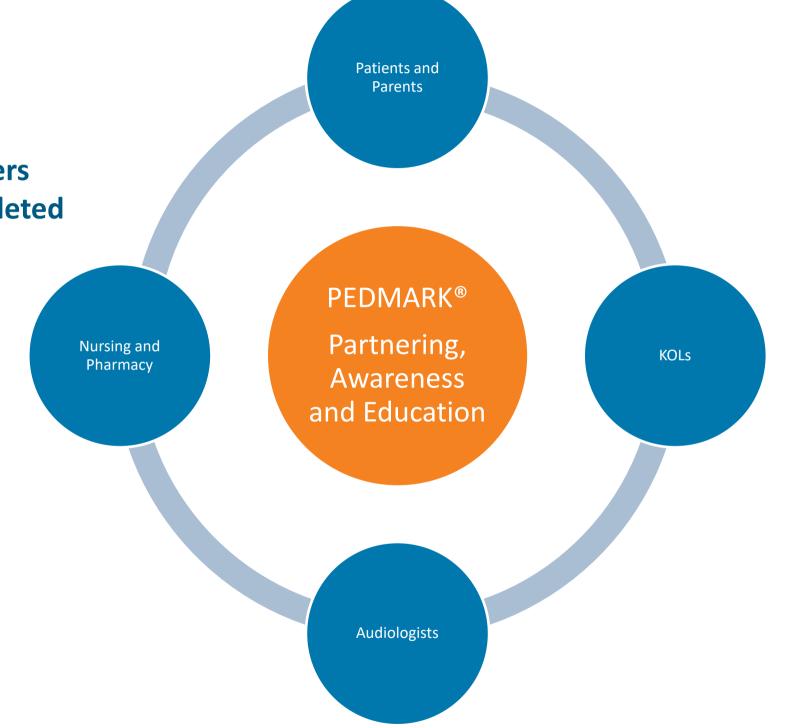


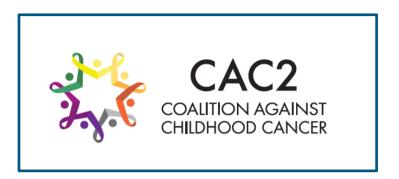
PEDMARK® (sodium thiosulfate injection):
Reducing the Risk of Ototoxicity Associated
With Cisplatin in Pediatric Patients 1 Month of Age and Older
with Localized, Non-metastatic Solid Tumors

Limitations of Use: The safety and efficacy of PEDMARK have not been established when administered following cisplatin
infusions longer than 6 hours. PEDMARK may not reduce the risk of ototoxicity when administered following longer cisplatin
infusions, because irreversible ototoxicity may have already occurred.



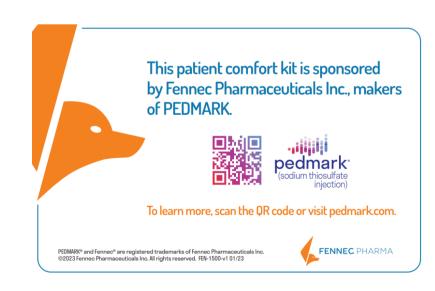












# FENNEC | Capital Structure and Financial Information

**Stock Listings Current** FENC – Nasdaq

FRX – TSX, Canada

**Shares Outstanding** 26.6 Million

Cash and Cash Equivalents\*1 USD \$56.0 Million

2023 Net Revenues<sup>2</sup> USD \$21.3 Million

2023 Cash Burn<sup>2</sup> USD \$16.0 Million

Debt<sup>3</sup> \$31.0 Million

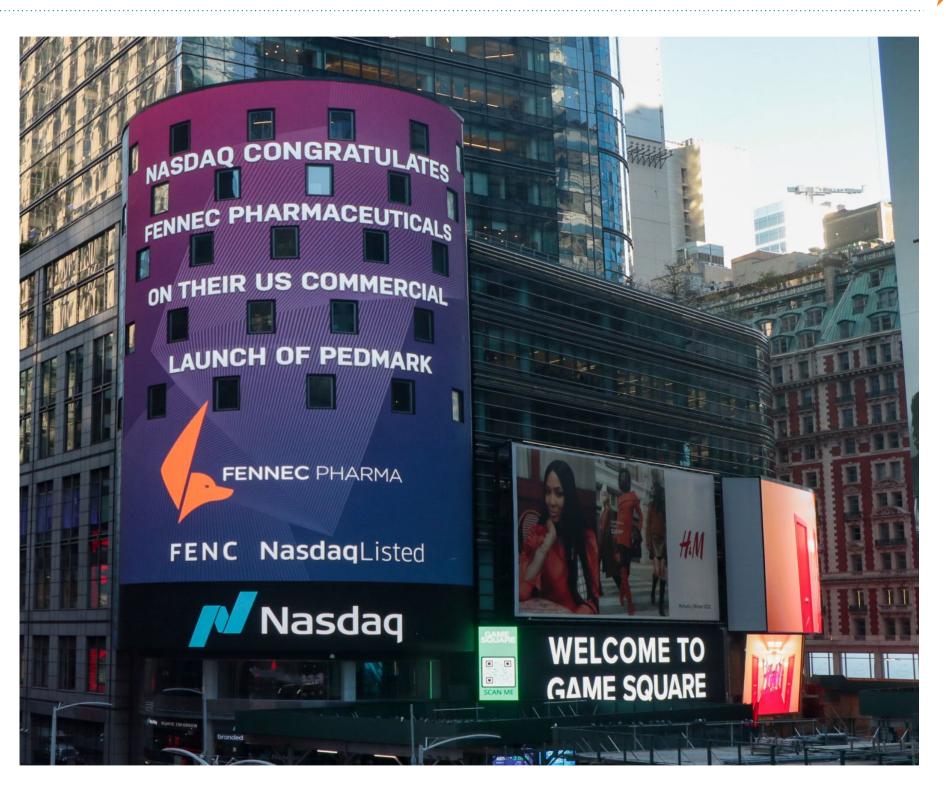
### INSTITUTIONAL OWNERSHIP<sup>4</sup>

**Southpoint Capital** 16%

Essetifin 16%

Sonic Fund 9%

<sup>\*</sup>On March 17, 2024, Fennec announced it received approximately \$43 million from the licensing of Europe, Australia and New Zealand to Norgine. Inclusive of these events, the pro forma December 31, 2023 cash balance is in excess of \$55 million



1. As of December 31, 2023. 2. For the 12-month period ending December 31, 2023. 3. As of December 31, 2023.

4. As of most recent Schedule 13G or Schedule 13F filing by respective fund.





#### **INDICATION & USAGE**

PEDMARK (sodium thiosulfate injection) is indicated to reduce the risk of ototoxicity associated with cisplatin in pediatric patients 1 month of age and older with localized, non-metastatic solid tumors.

#### Limitations of Use

The safety and efficacy of PEDMARK have not been established when administered following cisplatin infusions longer than 6 hours. PEDMARK may not reduce the risk of ototoxicity when administered following longer cisplatin infusions, because irreversible ototoxicity may have already occurred.

#### **IMPORTANT SAFETY INFORMATION**

PEDMARK is contraindicated in patients with history of a severe hypersensitivity to sodium thiosulfate or any of its components.

Hypersensitivity reactions occurred in 8% to 13% of patients in clinical trials. Monitor patients for hypersensitivity reactions. Immediately discontinue PEDMARK and institute appropriate care if a hypersensitivity reaction occurs. Administer antihistamines or glucocorticoids (if appropriate) before each subsequent administration of PEDMARK. PEDMARK may contain sodium sulfite; patients with sulfite sensitivity may have hypersensitivity reactions, including anaphylactic symptoms and life-threatening or severe asthma episodes. Sulfite sensitivity is seen more frequently in people with asthma.

PEDMARK is not indicated for use in pediatric patients less than 1 month of age due to the increased risk of hypernatremia or in pediatric patients with metastatic cancers.

Hypernatremia occurred in 12% to 26% of patients in clinical trials, including a single Grade 3 case. Hypokalemia occurred in 15% to 27% of patients in clinical trials, with Grade 3 or 4 occurring in 9% to 27% of patients. Monitor serum sodium and potassium at baseline and as clinically indicated. Withhold PEDMARK in patients with baseline serum sodium greater than 145 mmol/L.

Monitor for signs and symptoms of hypernatremia and hypokalemia more closely if the glomerular filtration rate (GFR) falls below 60 mL/min/1.73m2.

Administer antiemetics prior to each PEDMARK administration. Provide additional antiemetics and supportive care as appropriate.

The most common adverse reactions (≥25% with difference between arms of >5% compared to cisplatin alone) in SIOPEL6 were vomiting, nausea, decreased hemoglobin, and hypernatremia. The most common adverse reaction (≥25% with difference between arms of >5% compared to cisplatin alone) in COG ACCL0431 was hypokalemia.

Please see full Prescribing Information for PEDMARK at <a href="www.PEDMARK.com">www.PEDMARK.com</a>.

