



FENNEC PHARMA

**Corporate
Presentation**

October 2014

Safe Harbor Statement

During the course of this presentation we will make statements that constitute forward-looking statements. These statements may include operating expense projections, the initiation, timing and results of pending or future clinical trials, the actions or potential action of the FDA, the status and timing of ongoing research, corporate partnering activities and other factors affecting Fennec Pharma's financial condition or operations. Such forward looking statements are not guarantees of future performance and involve risk, uncertainties and other factors that may cause actual results, performance or achievements to vary materially from those expressed or implied in such statements. These and other risk factors are listed from time to time in reports filed with the SEDAR and the Securities and Exchange Commission, including but not limited to, reports on Forms 10-Q and 10-K. Fennec does not intend to update any forward looking information to reflect actual results or changes in the factors affecting forward-looking information.

Company Overview

- **Sodium Thiosulfate (STS)**
 - **Granted FDA Orphan Drug Designation – 7.5 yrs market exclusivity**
 - **European Market Exclusivity for Pediatric Use – 10 years**
 - **Positive data from two Phase 3 trials presented at ASCO June 2014**
 - **COG Study ACCL0431 – efficacy and safety data in localized disease**
 - **SIOPEL 6 – safety data in standard risk hepatoblastoma**
 - **Pending discussions with FDA and EMA – establish regulatory strategy in 2015**
- **US based - Headquarters in Research Triangle Park, NC**
- **Ticker: FENCF – USA, FRX – Toronto**
- **Market Cap: \$30 MM; 10 MM shares outstanding**
- **\$1.0 MM in cash at 6/30/14, no debt**

Platinum Hearing Loss is Frequent, Severe and Irreversible

Globally, ~7,000 children receive platinum based chemotherapy for localized cancers

- USA: 2,000 EU: 3,000 RoW: 2,000

40-90% develop profound irreversible ototoxicity*

- Ototoxicity is a dose-limiting side effect
- Effect can be seen after as little as the second or third dose
- Loss of high frequency hearing sensitivity (consonants /f/th/p/k/h/t)
- Background noise compounds disability in critical settings
- Infants and young children at critical stage of development lack speech language development and literacy
- Older children & adolescents lack social-emotional development and educational achievement



Devastating and life long impact on Quality of Life

*Neuwelt and Brock. J Clin Oncol 2010;28:1630-1632

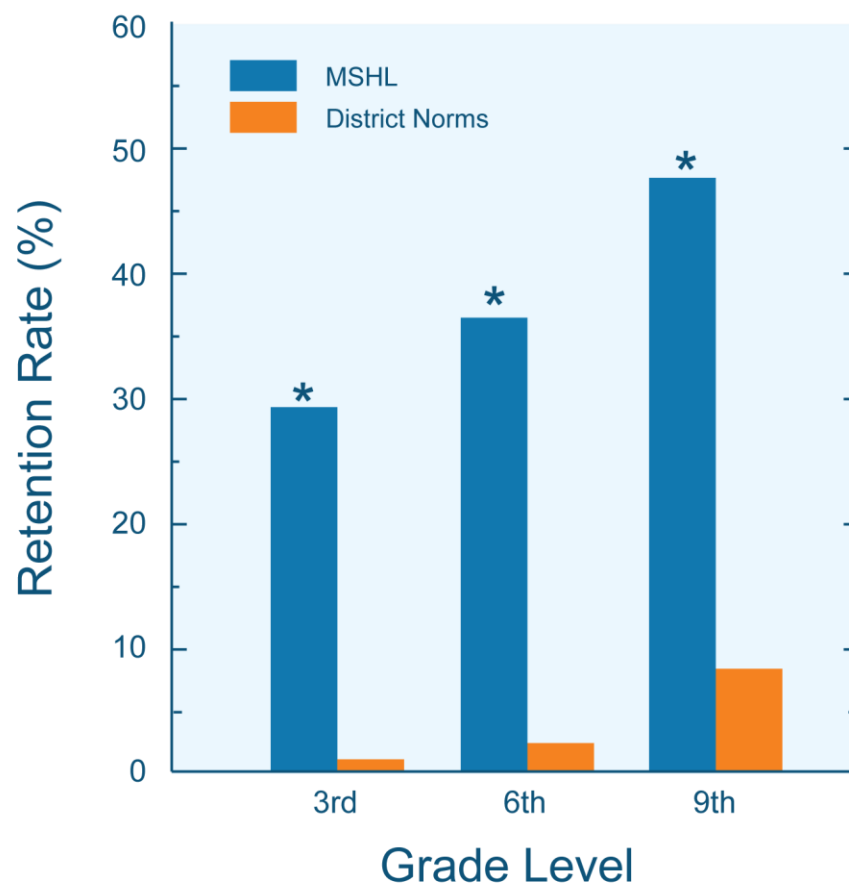
Devastating Impact on Quality of Life

Even minimal hearing loss (MSHL) is damaging

- High risk for being held back a grade (37% versus 3%)

Neuroblastoma survivors with hearing loss

- Twice the rate of parent reported problems with reading, math, attention and need for special education
- Poorer child-reported quality of life and school functioning



*Bess et al., Ear and Hearing, 1998, 19:339-54

*Gurney et al., Pediatrics, 2007 120(5):229-36

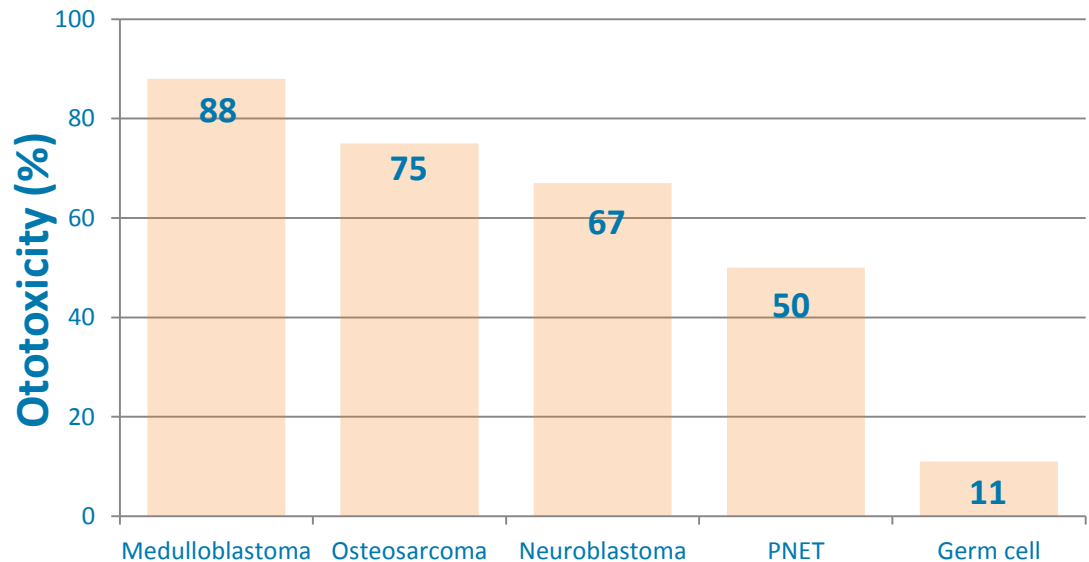
Ototoxicity in Children Treated with Cisplatin and/or Carboplatin*

61% bilateral hearing loss (ASHA criteria) at the end of treatment

41% required hearing aids that only partially restore hearing

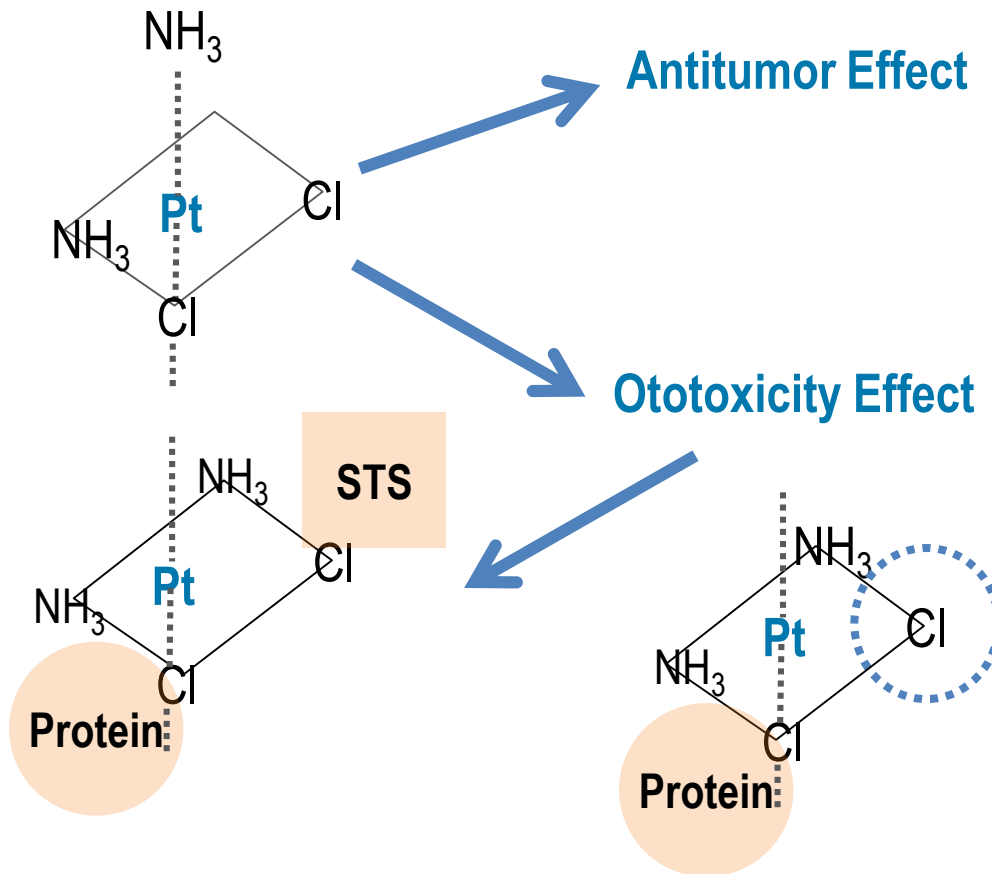
22% of patients had dose reductions due to ototoxicity

N=67 age 8 m -20 years



*Gilmer-Knight et al., Journal of Clinical Oncology

Target and Proposed STS Mechanism



- Requires both Cl unbound to crosslink DNA
- Binding to plasma proteins occurs within first hour which inactivates one binding site
- Free cDDP (unbound) short t_{1/2}: 1.5 hr
- Requires one Cl unbound to affect cochlear hair cells
- Binding to plasma proteins occurs within first hour which inactivates one binding site
- STS will bind second site preventing ototoxicity

COG ACCL0431: Randomized Phase 3 Study of STS for Prevention of Cisplatin-induced Hearing Loss

- Newly diagnosed children with hepatoblastoma, germ cell tumor, osteosarcoma, neuroblastoma, medulloblastoma, and others
- Local and metastatic disease
- Study Chair: David Freyer, DO, MS
- 135 randomized patients fully enrolled and study completed in 1Q 2012

Conclusions

- STS protects against cisplatin-induced hearing loss in children especially for those < 5 years old
- STS was not associated with decreased EFS/OS in patients with localized disease
- STS may lower survival among children with disseminated cancer

COG ACCL0431: Specific Aims

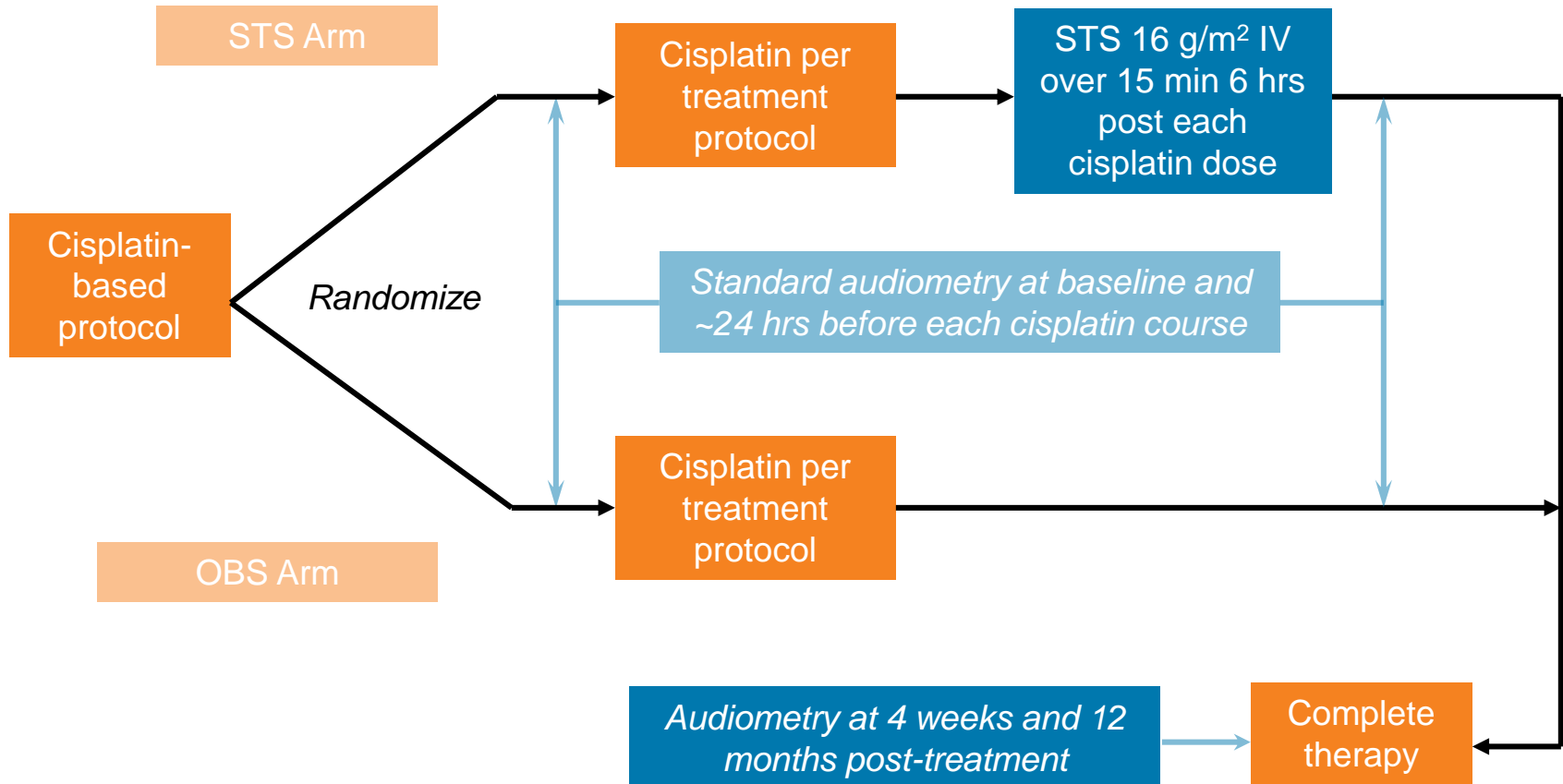
Primary

- Evaluate efficacy of STS for prevention of hearing loss in children receiving cisplatin chemotherapy (hypothesis: 50% relative reduction in hearing loss)

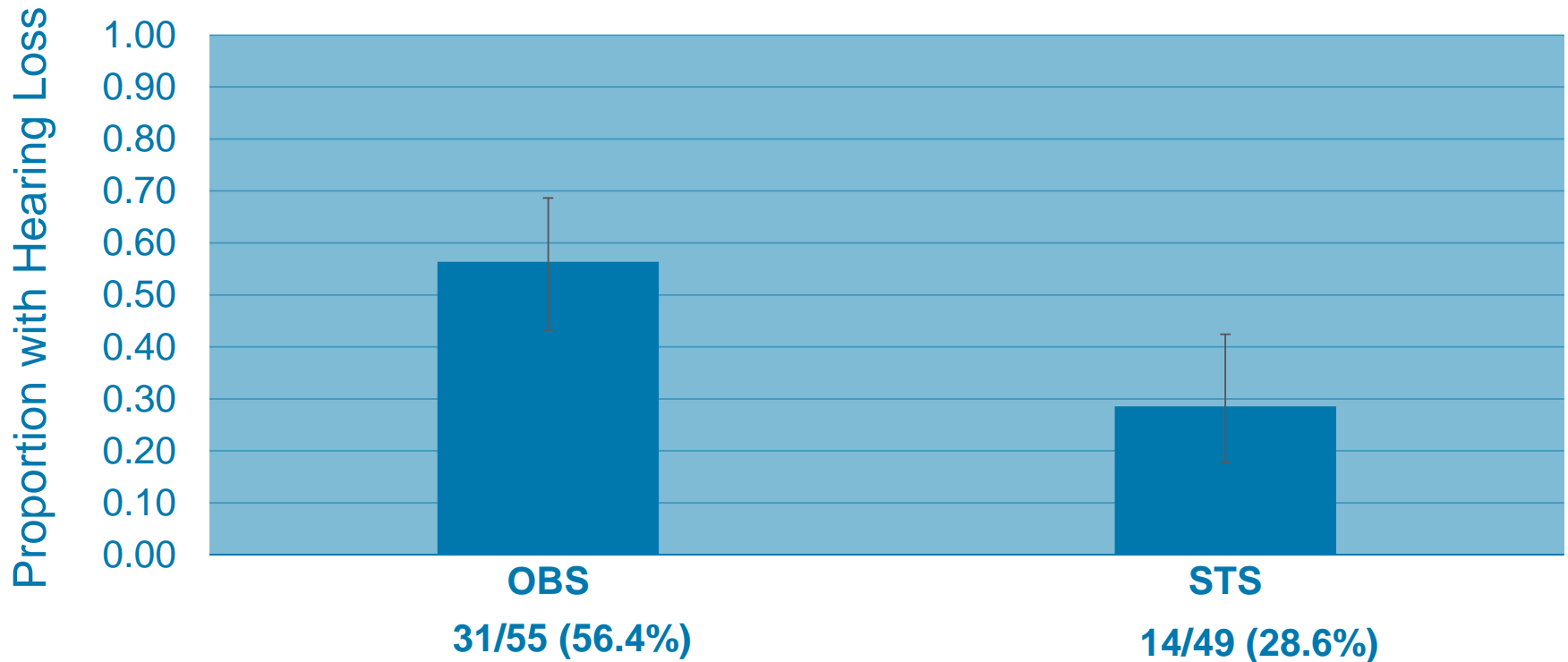
Secondary

- Compare change in mean hearing thresholds
- Compare incidence of other Grade 3/4 toxicities (renal and hematological)
- Monitor EFS and OS in two randomized groups

COG ACCL0431 Study Design

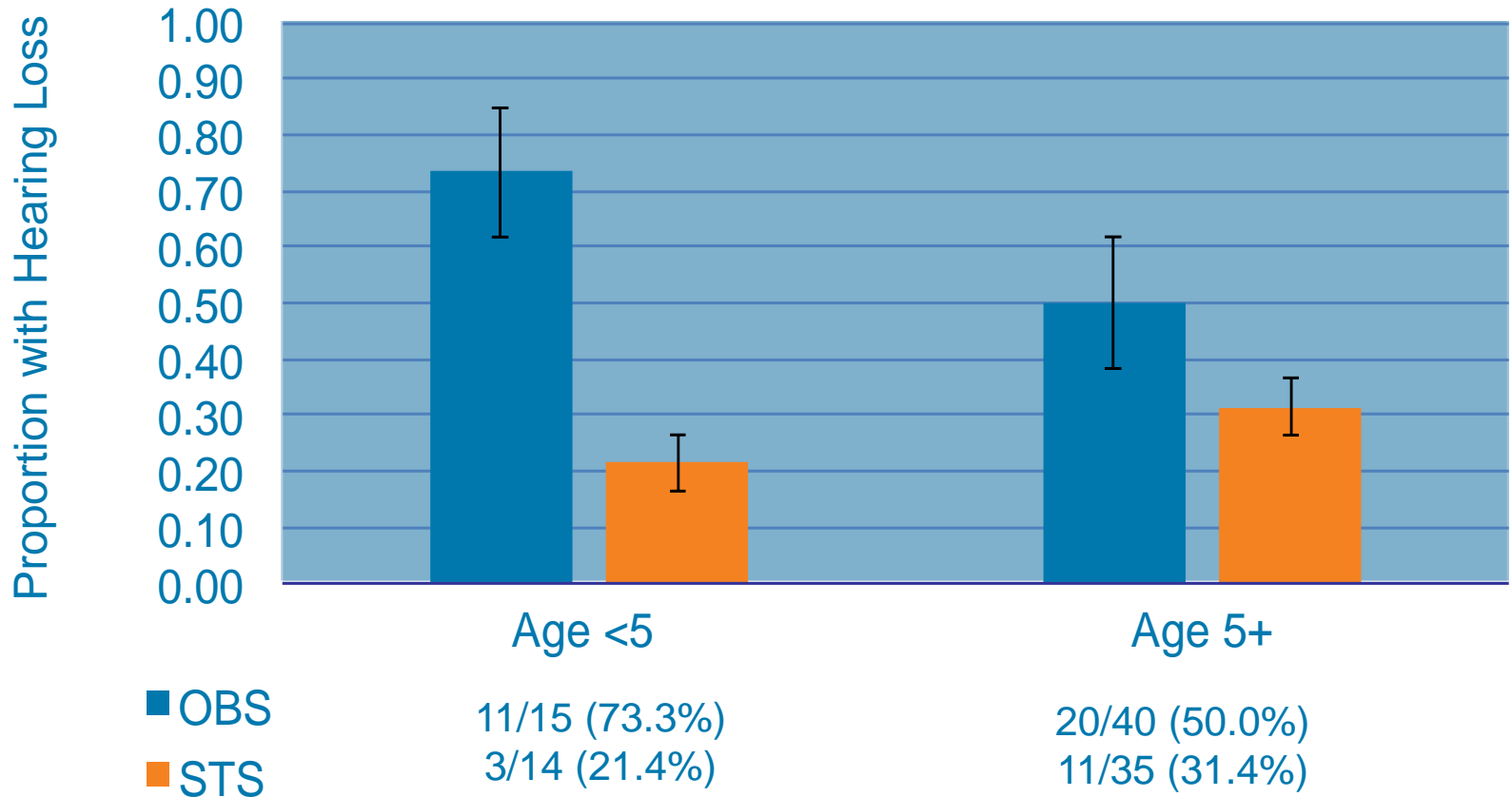


Hearing Loss By Randomized Arm



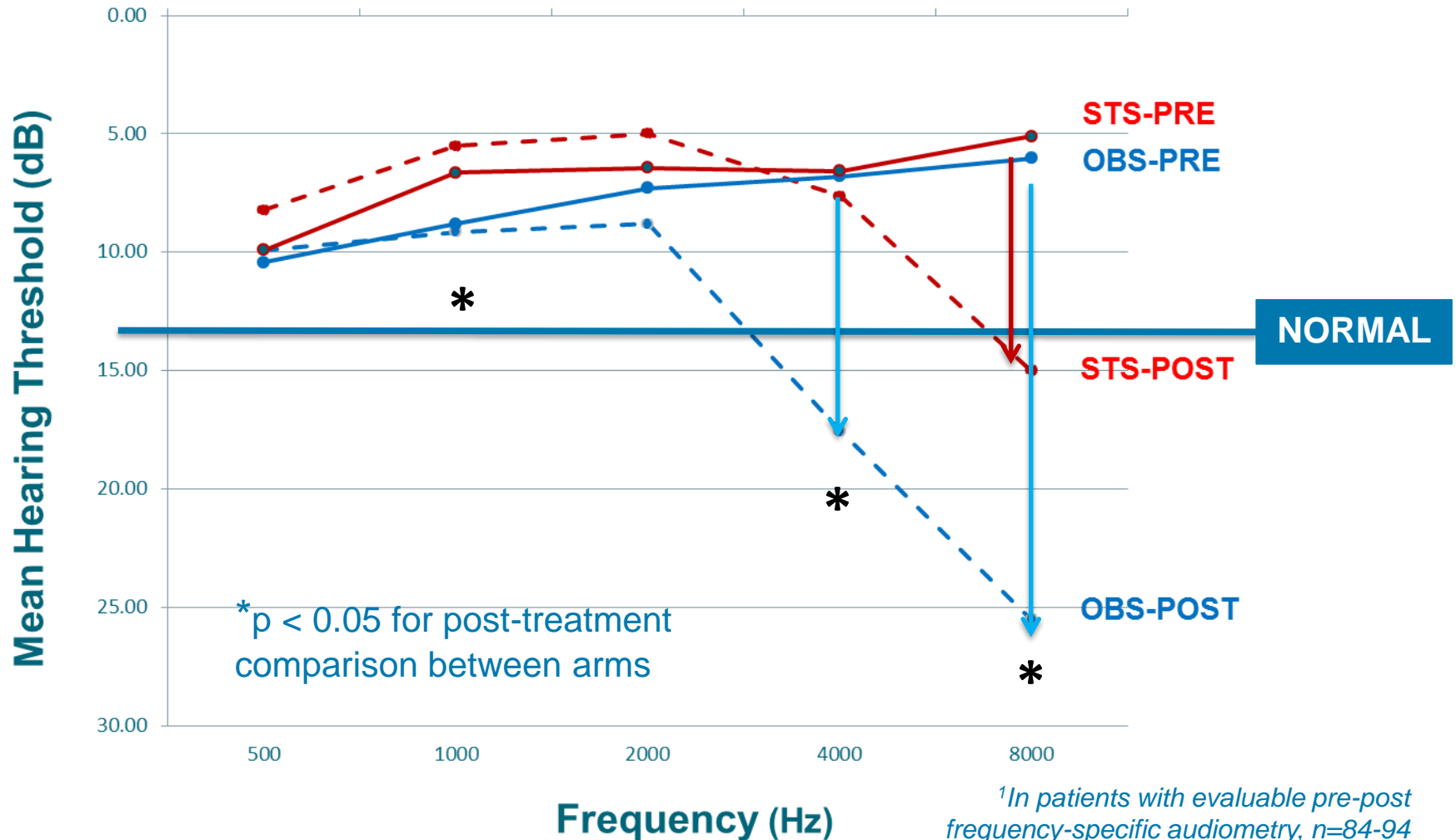
n=104 evaluable patients / p = 0.004

Hearing Loss By Randomized Arm and Age



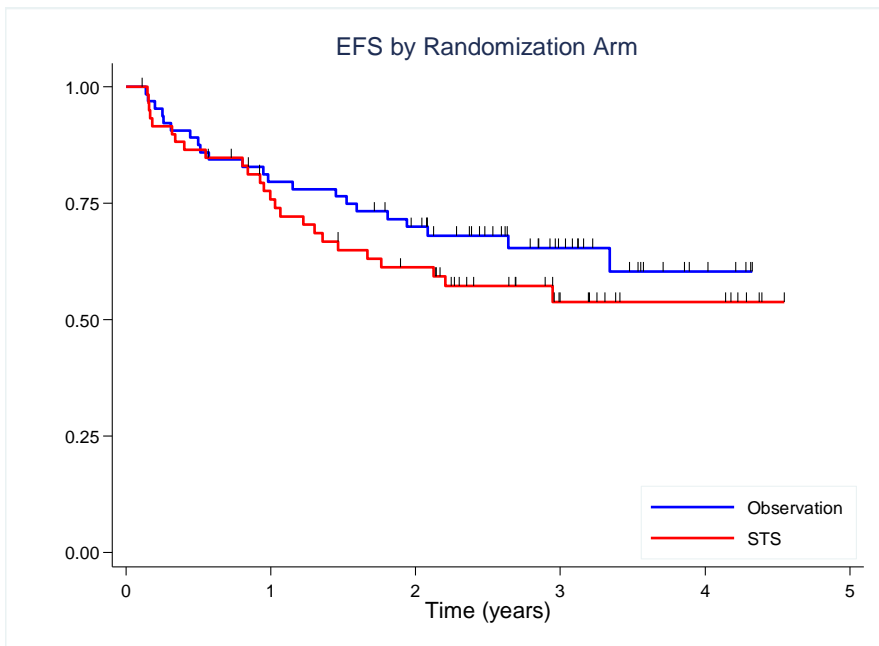
n=104 evaluable patients

Change in Mean Hearing Thresholds by Randomized Arm¹

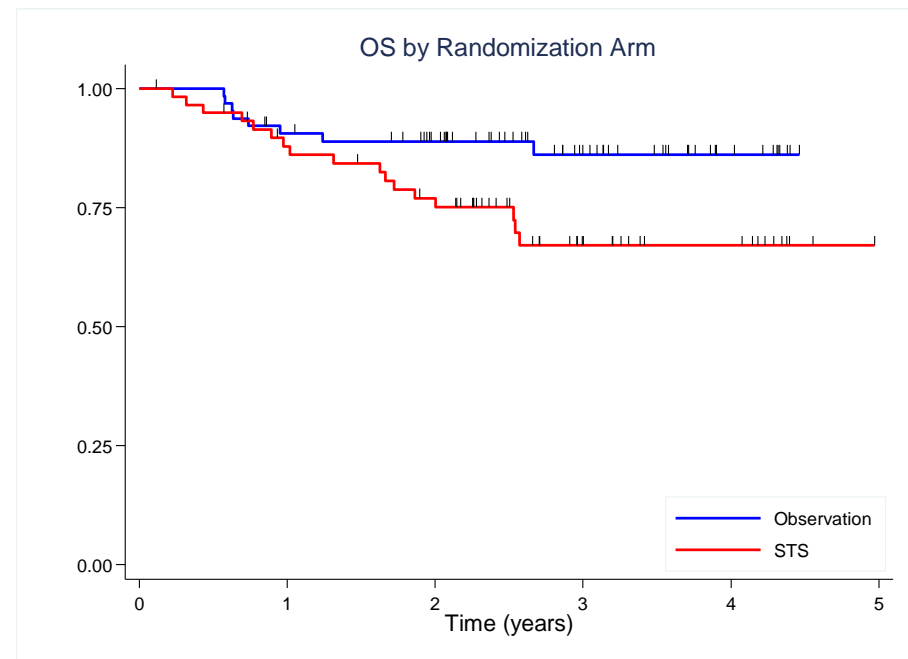


EFS/OS by Randomization Arm

All Patients, n=126 at median f/u of 2.9 yrs



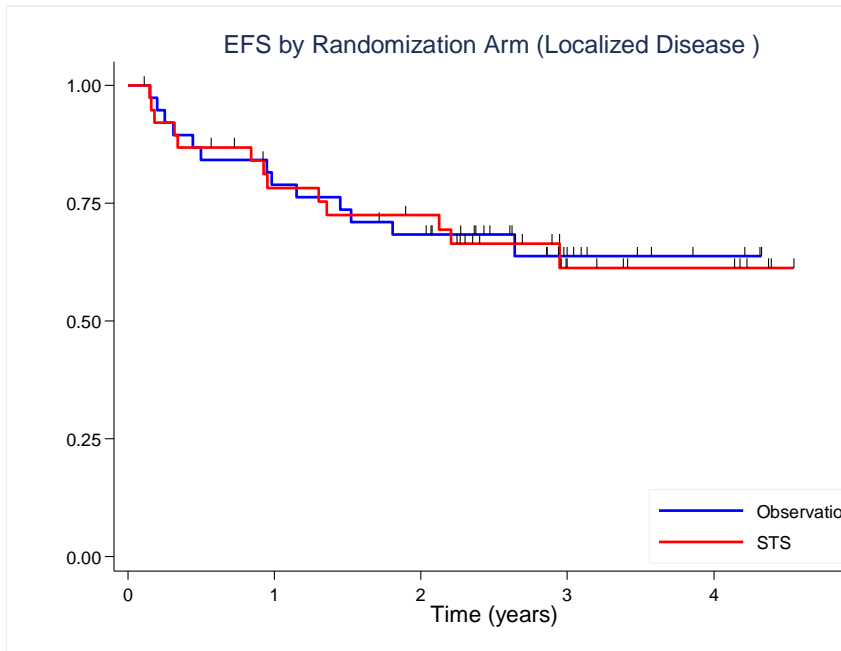
Log Rank $p = 0.31$



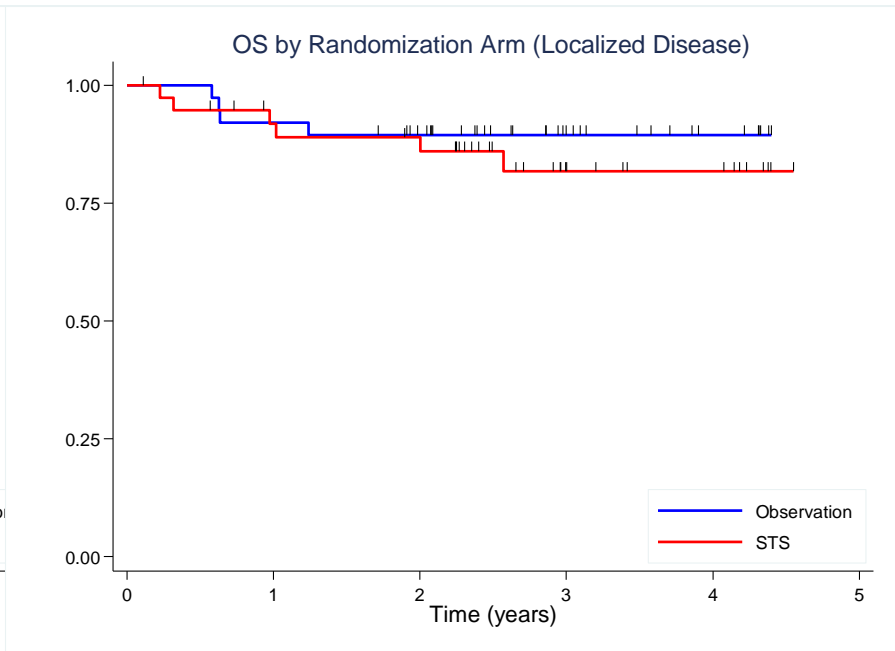
Log Rank $p = 0.03$

EFS/OS by Randomization Arm

Localized Disease Only, n=78



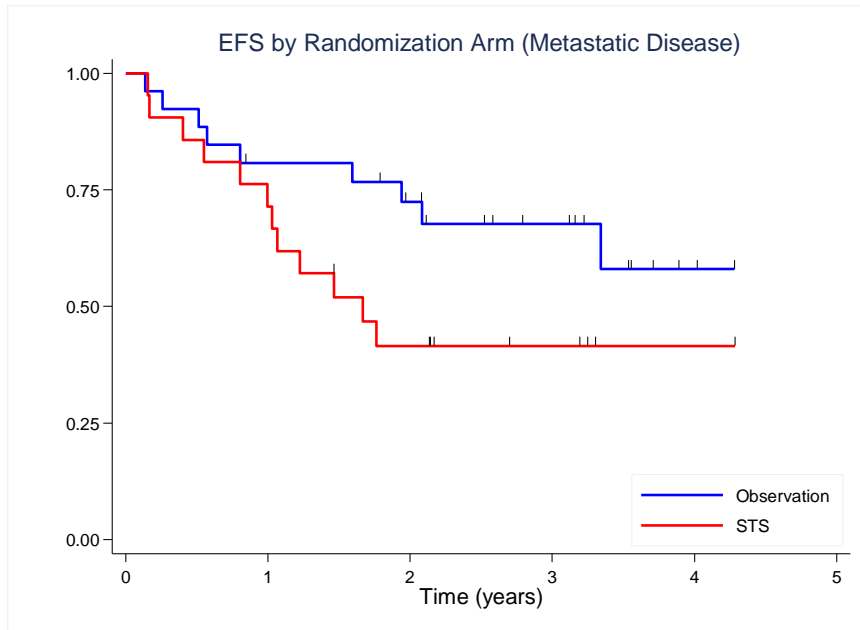
Log Rank $p = 0.94$



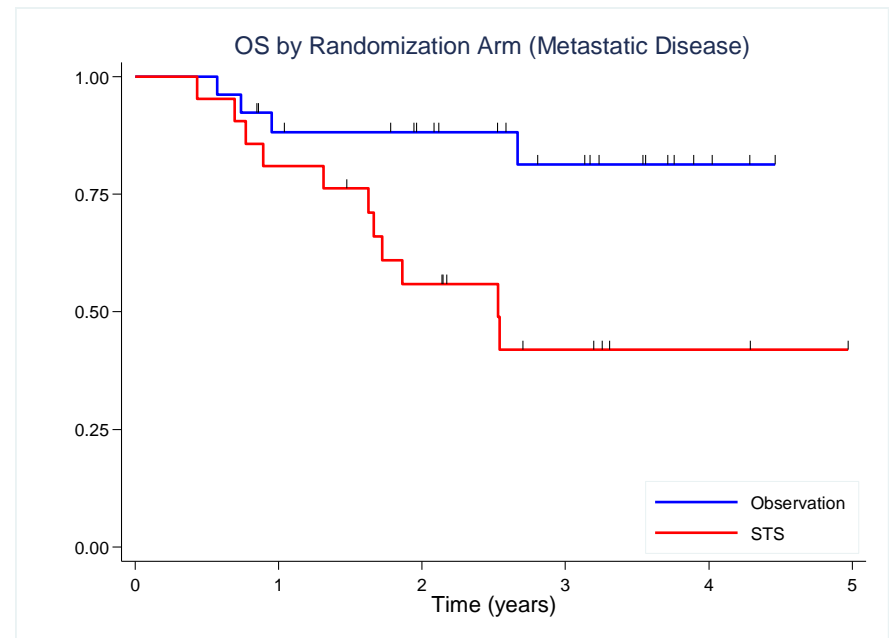
Log Rank $p = 0.48$

EFS/OS by Randomization Arm

Disseminated Disease Only, n=47

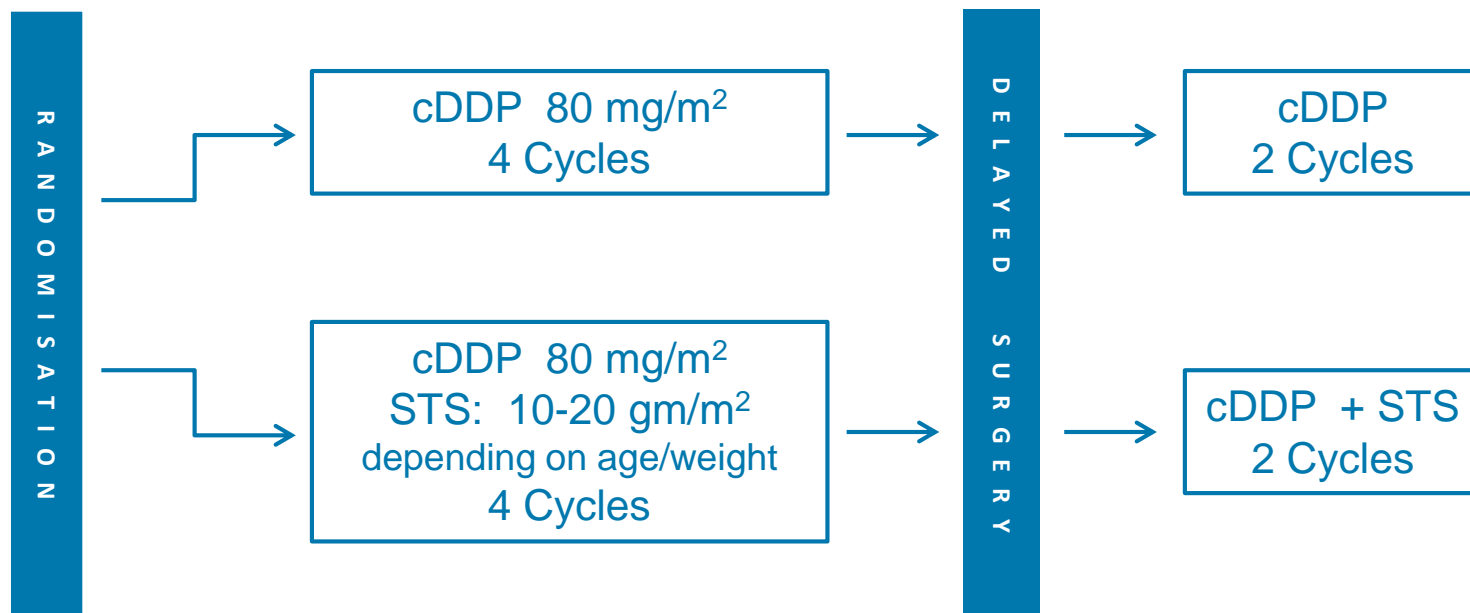


Log Rank $p = 0.085$



Log Rank $p = 0.011$

SIOPEL 6 - Efficacy of STS in Reducing Ototoxicity in Patients Receiving Cisplatin for Hepatoblastoma Patients



80% power to detect 60% vs 35% hearing loss

Two interim and one final efficacy analyses planned for early stopping in case of a greater than expected difference between treatment arms in terms of hearing loss

SIOPEL 6: Rand. Phase 3 Study - Efficacy of STS in Reducing Ototoxicity in Hepatoblastoma Patients

- Newly diagnosed children with standard risk hepatoblastoma
- Single localized disease with very high historic survival rates after cisplatin treatment
- Study Chair: Peppy Brock, MD
- 109 of 112 randomized patients
- STS does not appear to compromise safety in localized disease
- Interim safety analysis after 20, 40, 60 and 80 patients were conducted with DMC recommending study to continue

STS Market Opportunity

Pediatric Market Opportunity

- Approximately 2,000 children receive platinum-based chemotherapy for localized disease in the US each year
- Approximately 5,000 children receive platinum-based chemotherapy for localized disease in RoW each year

Competitive Position

- No alternative treatments available or in development
- Hearing aids and cochlear implants do not prevent hearing loss and cost \$2000 - \$6000 each (replaced every 5 years)
- Cochlear implants cost up to \$75,000 each

Market research confirms high unmet medical need

Market Research; Oncologists Comments

Pediatric oncologists were asked to comment on how the availability of STS would impact their treatment of patients.

Praise

- “This product will definitely [address unmet needs]. It would ***probably become standard front-line therapy.***”
- “This product sounds very good. If it really works, that’s great. I don’t know of any other way of protecting hearing. It’s new and different. ”
- “With the information given to me, it doesn’t seem like a bad drug. If all this data is true, it’s a 5 (excellent).”
- “***[I would prescribe to] anyone receiving cisplatin.*** Stage of disease doesn’t matter—I would prescribe to ***all patients.***”
- “Products S is going to ***allow us to be more aggressive with [platinum-based] agents.***”
- “If the clinical studies are convincing, and if this drug does not have any other side effects (besides what is noted in the product profile), and it does not affect the tumor’s response to chemotherapy, then I would like to ***use this product in 100% of my patients.***”

Concern

- “A major disadvantage would be finding out down the road that it does have ***adverse effects on treatment.***”
- “The only concern I have is that...we’re not ***compromising the chemotherapy*** while we’re trying to protect against ototoxicity.”

Market Research Payers Comments

Payers were asked to provide comments regarding potential STS coverage decisions.

STS Reimbursement

General Comments:

- “I think this could be the drug that changes how people practice. It would be malpractice NOT to use this when you’re giving platinum.”
- “This is truly an unmet need; I’d love to see the results of phase 3 trials ... This is something that would really be added benefit.”
- “STS is pretty unique. I didn’t realize hearing loss was such a huge issue. That’s impressive.”
- “Based on additional clinical information for adults (13% reduction in the need for hearing aids is not enough), we could decide to cover STS for children only.”

STS: Development Timeline

EVENT	TIMING
FDA Type C Clinical Development Meeting ✓	Mar 2011
Presented to Pediatric ODAC ✓ ODAC recognized challenge of demonstrating STS does not reduce efficacy of cisplatin and agreed adult study would not be appropriate	Nov 2011
COG ACCL0431 Phase 3 Clinical Data ✓	H1 2014
SIOPEL 6 Phase 3 Interim Safety Analysis (N=80)✓	H1 2014
FDA Pre NDA Meeting	H1 2015
NDA Submission	TBD
EU Pediatric Use Marketing Authorization Application	TBD

STS Investment Highlights

- Significant unmet medical need with no approved treatment on market or in development
- US Orphan Drug Designation (7.5 years market exclusivity)
- Positive data from COG Phase 3 trial in localized disease
- SIOPEL 6 safety data shows no tumor protective effect to this date (N=80)
- Pediatric Use Marketing Authorization in Europe (10 year market protection)
- Fennec has exclusive regulatory rights to data from both studies
- Use-patent as chemo-protectant in-licensed from OHSU
- Issued US, European and Japanese patents expire 2021, additional US pending prosecution
- Very small team required for commercialization
- Potential for Rare Pediatric Disease Voucher: upon approval of STS
 - 6 months priority review to any other new NDA or BLA application
 - Voucher can be transferred or sold with no restrictions
 - Similar voucher recently monetized by BioMarin for \$67.5 million

Management and Board of Directors

BOARD OF DIRECTORS

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Executive Development Advisor

Franck Rousseau, MD

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Lei Fang – Biostatistics

Kryisia Lynes – CFO

Anne McKay – Regulatory Affairs

Lex Smith – Pharmaceutical Development

Roy Swaringen – Chemical Development

Appendix: COG Patient Characteristics

Characteristic	Observation (%)	STS (%)
Eligible	64	62
Age at enrollment (yrs)		
< 5	22 (34.4)	22 (35.5)
≥ 5	42 (65.6)	40 (64.5)
Sex		
Male	41 (64.1)	35 (56.5)
Female	23 (35.9)	27 (43.5)
Race		
White	39 (60.9)	43 (69.4)
Black	10 (15.6)	5 (8.1)
Other/Unknown	15 (23.4)	14 (22.6)
Ethnicity - Hispanic	15 (23.4)	19 (30.7)

Target Enrollment: 135 / Enrolled: 131 / Eligible: 126

Appendix: Patient Characteristics, continued

Characteristic	Observation (%)	STS (%)
Diagnosis		
Germ Cell Tumor	16 (25.0)	16 (25.8)
Osteosarcoma	15 (23.4)	15 (24.2)
Medulloblastoma	14 (21.9)	12 (19.4)
Neuroblastoma	12 (18.8)	14 (22.6)
Hepatoblastoma	5 (7.8)	2 (3.2)
Other	2 (3.1)	3 (4.8)
Extent of Disease		
Localized	38 (59.4)	40 (64.5)
Disseminated	26 (40.6)	21 (33.9)
Unknown	0	1 (1.6)
Cum. CDDP dose (mg/m ²)	389 (198-1441)	393 (91-605)
Prior Cranial Irradiation	5	4