Trius Therapeutics

Best-in-Class Anti-Infectives

Tedizolid 112 Trial: Top Line Results Update

January 3, 2012

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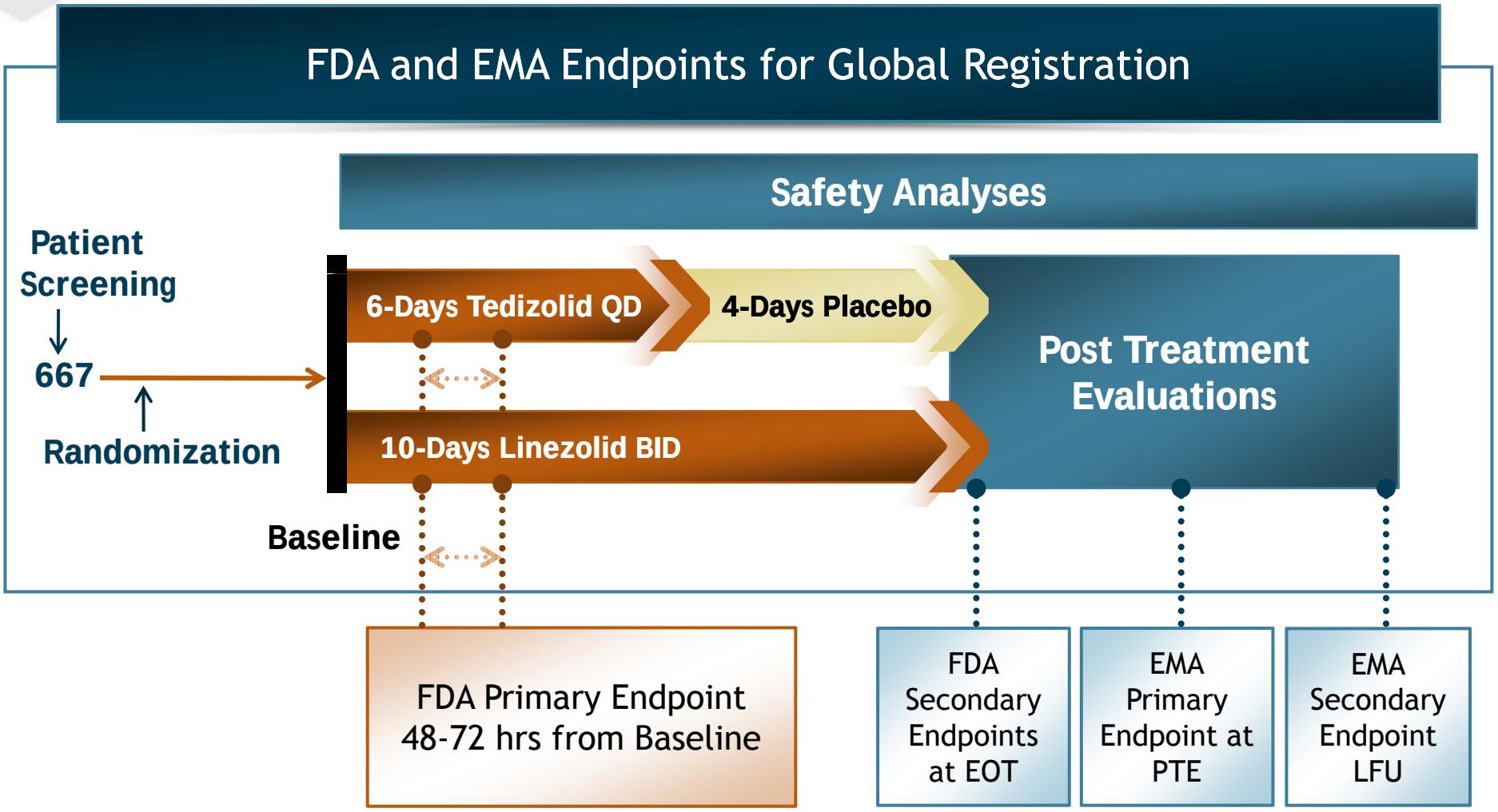
Progression of ABSSSI Regulatory Environment for Phase 3 Studies 112 and 113

- May 2010: First in a series of FDA requested meetings of the FNIH (Foundation for the National Institutes of Health) working group established to provide recommendations to the FDA on endpoints for clinical trials of drugs for ABSSSI and other indications
- June 2010: FDA grants Trius a "SPA Letter of Agreement" for study #112
- August 2010:
  - FDA issues "Draft ABSSSI guidance" that reflect changes from the 112 SPA including:
    - Carry-over of early failures at secondary outcome measurement and exclusion of investigator-reported pain at EOT as a secondary outcome failure criterion
- August 2011:
  - FDA grants Trius an SPA agreement for study #113 that reflects the recent draft guidance
  - FNIH submits to the FDA its recommendations on ABSSSI guidance (ABSSSI Docket ID: FDA--2011--D--0433). The recommendations include:
    - Removal of fever as a component of the primary endpoint leaving cessation of spread & reduction in lesion size as the sole parameters for the primary efficacy analysis at the 48-72hr visit
    - Recommendation to also use ≥ 20% reduction of lesion size at 48-72hrs as the primary outcome

Trius has prospectively captured these suggested changes in the analyses of studies 112 and 113

- Q2 2012: Expected issuance of final guidance on ABSSSI

Tedizolid Phosphate Phase 3 Study Design: Oral (112) and IV/Oral (113) Trials Under SPA



Study 112 Primary & Secondary Endpoints: Capturing FDA and EMA Endpoints

Primary Endpoint*:

- Cessation of lesion spread & resolution of fever at 48-72 hour visit after initiation of study drug (ITT analysis set) [FDA Primary Endpoint]

Secondary Endpoints:

- Sustained clinical response at EOT in the ITT analysis set (days 11-13)
- Sustained clinical response at EOT in the CE-EOT analysis set (days 11-13)
- Investigator's assessment of clinical success at PTE in the ITT analysis set (days 17-24) [EMA Primary Endpoint]
- Investigator's assessment of clinical success at PTE in the CE analysis set (days 17-24)

**Study 112 was 90% powered for a 10% NI margin if both treatment groups had ~ 81% outcome rate. It had 80% power for an outcome rate as low as 70%.*

Primary Outcome: All Current and Contemplated Trial 112 Primary Endpoints Achieved in Pre-Specified Analyses

Primary Outcome at 48-72 hour visit		Treatment	
Lesion Criteria	Fever Criteria	**Tedizolid** (200 mg QD 6 days)	**Linezolid** (600 mg BID 10 days)
No increase in lesion area from baseline*	Temperature measurements required within 24 hrs of 48-72 hr visit*	79.5%	79.4%

FNIH recommended to FDA to exclude temperature as a component of the primary endpoint and to assess a ≥20% reduction in lesion size at 48 to 72 hours.
Under these pre-specified analysis tedizold shows additional numerical separation from linezolid

No increase in lesion area from baseline	Temperature excluded**	87.0%	85.4%
≥ 20% reduction of lesion area from baseline**	Temperature excluded**	78.0%	76.1%

* Primary endpoint as agreed to under Study 112 and 113 SPA
** FNIH recommendations to FDA: ABSSSI Docket ID: FDA--2010--D--0433

Secondary Outcomes: Tedizolid Demonstrates Comparable Efficacy with Shorter Course of Therapy

Secondary Outcome at EOT or PTE		Treatment	
Secondary Outcome	Criteria	**Tedizolid** (200 mg QD 6 days)	**Linezolid** (600 mg BID 10 days)
Clinical Response at EOT* (Day 11)	Early clinical failures carried forward to EOT*	69.3% (ITT)	71.9% (ITT)
		80.2% (CE)	81.1% (CE)

In August 2010 draft guidance the FDA adopted changes to the secondary outcomes of clinical response at the end of therapy (EOT). These were prospectively measured in Study 112 sensitivity analyses and are captured in the Study 113 SPA.

Clinical Response at EOT* (Day 11)	Early clinical failures not carried forward to EOT**	80.7% (ITT)	80.9% (ITT)
		87.5% (CE)	87.1% (CE)
Clinical Response at EOT* (Day 11)	Early clinical failures not carried forward to EOT** and presence/absence of patient reported pain at EOT excluded*/**	87.0% (ITT)	87.8% (ITT)
		94.5% (CE)	95.1% (CE)

* Primary and secondary endpoints as agreed to under Study 112 SPA

** Consistent with FDA draft ABSSSI Guidance for Industry (August 2010)

EMA Endpoint: A Once-Daily 200mg Dose of Tedizolid for 6 Days Demonstrates Comparable Efficacy to Twice-Daily 600mg Dose of Linezolid for 10 Days of Treatment

Secondary Outcome at PTE		Treatment	
Secondary Outcome	Criteria	Tedizolid (200 mg QD 6 days)	Linezolid (600 mg BID 10 days)
Clinical Response at PTE* (Day 17-24)	Clinician assessment at PTE	85.5% (ITT)	86.0% (ITT)
		94.6% (CE)	95.0% (CE)

* EMA primary endpoint (EMA Report on the workshop on Antibacterials issued March 2011). Captured in both the Study 112 and 113 SPA

Shorter Course of Tedizolid Therapy Shows Comparable Per Pathogen Clinical Response

Clinical investigator's assessment of clinical response at Post Treatment Evaluation (days 17-24) in the Microbiological Evaluable analysis set

Pathogen	Tedizolid (200mg QD 6 days)	Linezolid (600mg BID 10 days)
Staphylococcus **spp.**	283/295 (96%)	300/302 (99%)
MRSA	73/78 (94%)	74/75 (99%)
MSSA	65/66 (99%)	75/75 (100%)
Other	7/7 (100%)	4/4 (100%)
Streptococcus **spp.**	34/35 (97%)	27/29 (93%)

Tedizolid was Well Tolerated with a Favorable AE Profile Compared to Linezolid

Tedizolid had a numerically lower rate of drug-related treatment emergent adverse events (TEAE) and a statistically significant lower number of gastrointestinal adverse events

Adverse Event	Tedizolid (200mg QD 6 days)	Linezolid (600mg BID 10 days)
Any Treatment Emergent Adverse Event (TEAE)	40.8%	43.3%
Any Drug Related TEAE	24.2%	31.0%
Gastrointestinal Disorders*	16.3%**	25.4%

* *Gastrointestinal AEs include: Diarrhea, Nausea, Vomiting and Dyspepsia*

** *Statistically significant (p=0.004).*

No Unexpected Safety Signals

- Liver enzymes/function tests
- QTc

Hematology: Tedizolid had Significantly Lower Impact on Platelets than Linezolid

	Percent of Patients with Value below the Lower Limit of Normal (LLN)	
Hematology Parameter	Tedizolid (200mg QD 6 days)	Linezolid (600mg BID 10 days)
Platelets* Below LLN	9.2%	14.9%
Platelets - Substantially abnormal value (<75% of LLN)	2.3%	4.9%

* Statistically significant (p=0.038)

Summary

- Phase 3 trials conducted under new FDA ABSSSI guidance are manageable
- Study 112 design and outcomes will satisfy both FDA and EMA regulatory requirements
- All efficacy and safety objectives of Study 112 were successfully achieved
  - Efficacy: All primary and secondary trial endpoints met with a once-daily short course of therapy
  - Safety: statistically significant lower incidence in key tolerability and safety parameters

Upcoming Milestones

- ✓ Top line data from 112 Phase 3 ABSSSI trial
- SPA for and initiation of Phase 3 pneumonia study
- Potential partner for Europe
- Initiation of clinical studies for Gyrase
- Completion of enrollment for 113 Phase 3 ABSSSI trial