Trius Therapeutics

The Future of Anti-Infectives

# ESTABLISH 2 Top Line Data Release

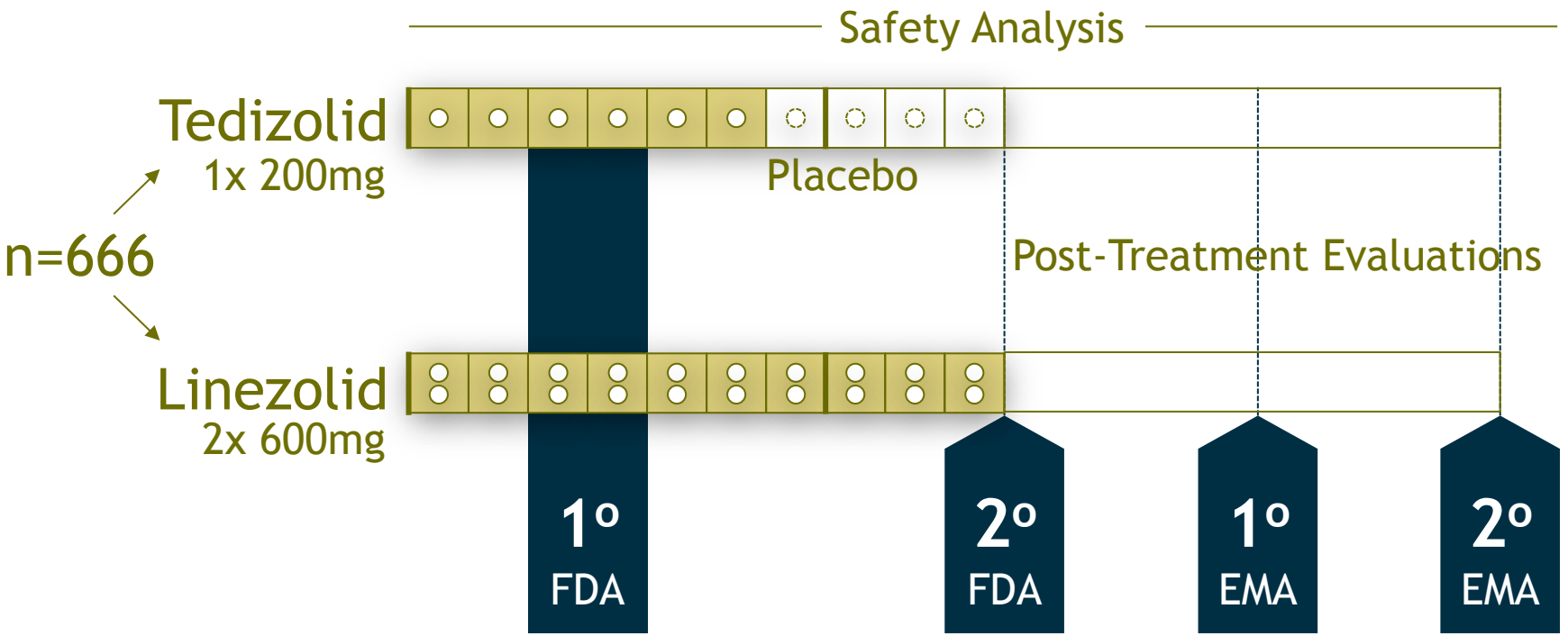
March 25, 2013

# Forward Looking Statements

Statements contained in this data release regarding matters that are not historical facts are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Risks that contribute to the uncertain nature of the forward-looking statements include: the accuracy of Trius’ estimates regarding expenses, future revenues and capital requirements; the success and timing of Trius’ preclinical studies and clinical trials; regulatory developments in the United States and foreign countries; changes in Trius’ plans to develop and commercialize its product candidates; Trius’ ability to obtain additional financing; Trius’ ability to obtain and maintain intellectual property protection for its product candidates; and the loss of key scientific or management personnel. These and other risks and uncertainties are described more fully in Trius’ most recently filed SEC documents, including its Form 10-K, Forms 10-Q and other documents filed with the United States Securities and Exchange Commission, including those factors discussed under the caption “Risk Factors” in such filings. All forward-looking statements contained in this press release speak only as of the date on which they were made. Trius undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

# ESTABLISH 2 (IV/PO) Phase 3 Trial Design

## Non-inferiority trial design vs Linezolid




## END-POINTS FOR GLOBAL REGISTRATION

# ESTABLISH 2 Primary & Secondary Endpoints

**Primary Endpoint:**

- 20% or greater reduction in lesion area at 48-72 hours after first dose of drug

**Secondary Endpoints:**

- Programmatic clinical response at end of therapy (EOT)
- Investigator's assessment of clinical response at post treatment evaluation (PTE)

# ESTABLISH 2 Demographics and Baseline Characteristics

| | **Tedizolid, %** n = 332 | **Linezolid, %** n = 334 |
|---|---|---|
| Male, % | 67.8 | 64.1 |
| Age, mean | 45.6 | 45.6 |
| | | |
| Geographic Region, % | | |
| North America (US) | 47.0 | 47.3 |
| Ex-U.S. | 53.0 | 52.7 |
| | | |
| Clinical Syndrome, % | | |
| Cellulitis/erysipelas | 50.0 | 50.3 |
| Major abscess | 20.5 | 20.4 |
| Wound infection | 29.5 | 29.3 |
| | | |
| MRSA (MITT), % | 27.2 | 26.9 |
| MSSA (MITT), % | 52.8 | 53.0 |
| | | |
| Lymphadenopathy, % | 70.8 | 70.4 |
| WBC < 4,000 or > 10,000, % | 53.0 | 45.2 |
| Immature neutrophils, % | 16.2 | 12.2 |
| Fever, % | 31.0 | 29.0 |

# ESTABLISH 2 Efficacy

| ITT Analysis Set | Endpoint | **Tedizolid** 6 days treatment, % n = 332 | **Linezolid** 10 days treatment, % n = 334 | Treatment Difference (95% CI), % |
|---|---|---|---|---|
| **Primary Endpoint** | ≥20% decrease from baseline in lesion area at 48-72 hours | 85.2 | 82.6 | 2.6 (-3.0 to 8.2) |
| **Key Secondary Endpoints** | Sustained clinical response at end of therapy | 87.0 | 88.0 | -1.0 (-6.1 to 4.1) |
| | Investigators assessment of clinical response at 7-14 days after end of therapy | 88.0 | 87.7 | 0.3 (-4.8 to 5.3) |
| **Sensitivity analysis (2010 Guidance)** | Cessation of lesion spread and absence of fever at 48-72 hrs | 85.8 | 81.4 | 4.4 (-1.2 to 10.1) |

# ESTABLISH 2 Efficacy by Infection Type

| ITT Analysis Set | **Tedizolid** 6 days treatment, % n = 332 | **Linezolid** 10 days treatment, % n = 334 | Treatment Difference (95% CI), % |
|---|---|---|---|
| **Cellulitis/erysipelas** | 80.7 n = 166 | 80.4 n = 168 | 0.37 (-8.2 to 8.9) |
| **Major cutaneous abscess** | 86.8 n = 68 | 89.7 n = 68 | -2.9 (-14.5 to 8.4) |
| **Wound infection** | 91.8 n = 98 | 81.6 n = 98 | 10.2 (0.71 to 20.1) |

# ESTABLISH 2 Safety: Tedizolid was Safe and Well Tolerated with a Favorable AE Profile vs Linezolid

| Safety Analysis Set | **Tedizolid**<br>6 days treatment, % | **Linezolid**<br>10 days treatment, % |
|---|---|---|
| **Any Treatment Emergent Adverse Event (TEAE)** | 45.3 | 43.7 |
| **Any Drug Related TEAE** | 20.5 | 24.8 |
| **Gastrointestinal Disorders** | 16.0 | 20.5 |

No Safety Signals

# ESTABLISH 2 Incidence of TEAEs >2%

| System Organ Class | Tedizolid, (%) n = 331 | Linezolid, (%) n =327 |
|---|---|---|
| Gastrointestinal disorders | 53 (16.0) | 67 (20.5) |
| General disorders and administration site conditions | 23 (6.9) | 24 (7.3) |
| Infections and infestations | 40 (12.1) | 40 (12.2) |
| Metabolism and nutrition disorders | 9 (2.7) | 7 (2.1) |
| Musculoskeletal and connective tissue disorders | 9 (2.7) | 9 (2.8) |
| Nervous system disorders | 29 (8.8) | 36 (11.0) |
| Psychiatric disorders | 10 (3.0) | 4 (1.2) |
| Respiratory, thoracic and mediastinal disorders | 6 (1.8) | 13 (4.0) |
| Skin and subcutaneous tissue disorders | 21 (6.3) | 24 (7.3) |
| Vascular disorders | 7 (2.1) | 4 (1.2) |

# ESTABLISH 2 Post-Baseline Substantially Abnormal Hematology Values

| | Tedizolid, (%)<br>n = 331 | Linezolid, (%)<br>n =327 |
|---|---|---|
| **Hemoglobin** | 292 | 287 |
| Below LLN | 147 (50.3) | 148 (51.6) |
| Substantially abnormal | 4 (1.4) | 2 (0.7) |
| **White blood cells** | 272 | 258 |
| Below LLN | 16 (5.9) | 20 (7.8) |
| Substantially abnormal | 3 (1.1) | 5 (1.9) |
| **Platelets** | 275 | 269 |
| Below LLN | 37 (13.5) | 35 (13.0) |
| Substantially abnormal | 9 (3.3) | 5 (1.9) |

# Differences Between ESTABLISH 1 and 2

| | ESTABLISH 2 | ESTABLISH 1 |
|---|---|---|
| **Dosing** | IV to oral (minimum 1st day's dosing IV) | Oral |
| **Demographics** | US 47%, x-US 53% | US 80%, x-US 20% |
| **MRSA, %** | 27.1 | 42.6 |
| **Primary Endpoint*** | ≥ 20% reduction in lesion area @ 48 to 72 hrs | Cessation of lesion spread, absence of fever @ 48 to 72 hrs |

*ESTABLISH 2 SPA amended under agreement with FDA to reflect expected new primary endpoint. Both endpoints prospectively captured as sensitivity analyses in respective studies. Integrated summary of efficacy will reflect the ESTABLISH 2 primary endpoint under the amended SPAs

# ESTABLISH Program Comparison

| Endpoint | Study | **Tedizolid** 6 days treatment, % | **Linezolid** 10 days treatment, % | Treatment Difference (95% CI), % |
|---|---|---|---|---|
| ≥20% decrease from baseline in lesion area at 48-72 hours | ESTABLISH 2<br>ESTABLISH 1 | 85.2<br>78.0 | 82.6<br>76.1 | 2.6 (-3.0 to 8.2)<br>1.9 (-4.5 to 8.3) |
| Sustained clinical response at end of therapy | ESTABLISH 2<br>ESTABLISH 1 | 87.0<br>87.0 | 88.0<br>87.8 | -1.0 (-6.1 to 4.1)<br>-0.8 (-5.8 to 4.4) |
| Investigators assessment of clinical response at 7-14 days after end of therapy | ESTABLISH 2<br>ESTABLISH 1 | 88.0<br>85.5 | 87.7<br>86.0 | 0.3 (-4.8 to 5.3)<br>-0.5 (-5.8 to 4.9) |
| Cessation of lesion spread and absence of fever at 48-72 hrs | ESTABLISH 2<br>ESTABLISH 1 | 85.8<br>79.5 | 81.4<br>79.4 | 4.4 (-1.2 to 10.1)<br>0.1 (-6.1 to 6.2) |

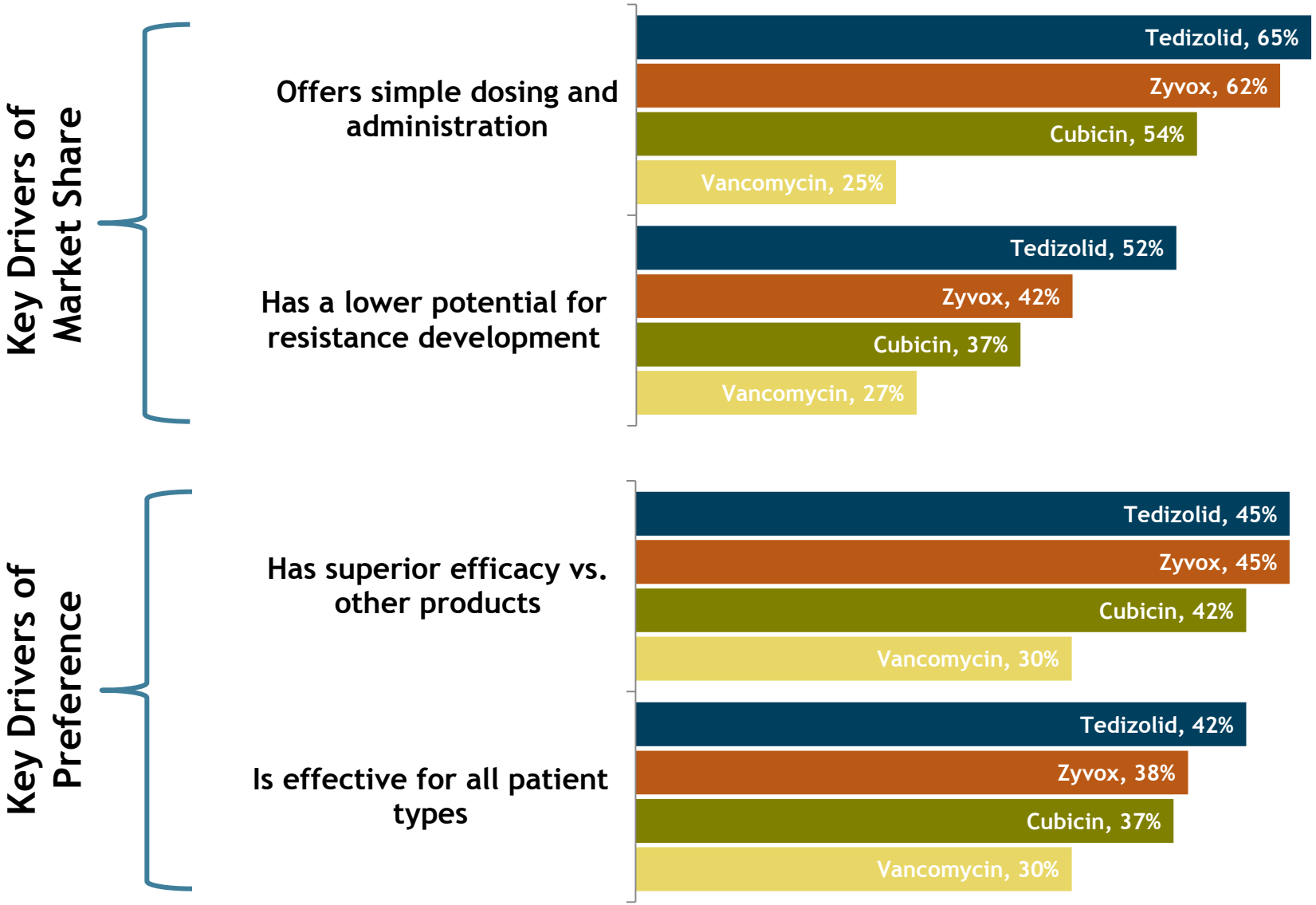
# ESTABLISH Program Safety Comparison

| Safety Analysis Set | Study | Tedizolid % | Linezolid % |
|---|---|---|---|
| Any Treatment Emergent Adverse Event (TEAE) | ESTABLISH 2 | 45.3 | 43.7 |
| | ESTABLISH 1 | 40.8 | 43.3 |
| Any Drug Related TEAE | ESTABLISH 2 | 20.5 | 24.8 |
| | ESTABLISH 1 | 24.2 | 31.0 |
| Gastrointestinal Disorders | ESTABLISH 2 | 16.0 | 20.5 |
| | ESTABLISH 1 | 16.3 | 25.4 |

# Summary

- All primary and secondary efficacy endpoints were met for FDA and EMA
- Safety profile indicated that tedizolid was safe and well tolerated
- Results are consistent with those from ESTABLISH 1 and support filings for global regulatory approval
- Combined results of all clinical studies support tedizolid differentiation:
  - Safe, well tolerated, fast acting drug for resistant gram positive infections
  - Convenient once daily IV or oral administration over short course of therapy
  - Fewer drug-drug interactions
  - Active against key linezolid resistant strains

# Strong Response to Tedizolid Efficacy, Dosing and Administration*



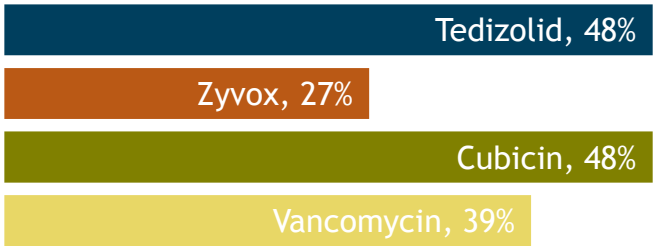

**Efficacy performance ratings among those aware of brand*

*Tedizolid ATU Study, Wave 1 – USA Report, conducted by CMI on behalf of Trius, November 2012, N=505*

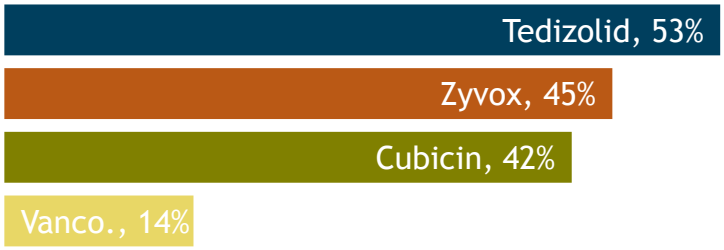
# Strong Response to Tedizolid Safety & Tolerability

**Key Drivers of Market Share**

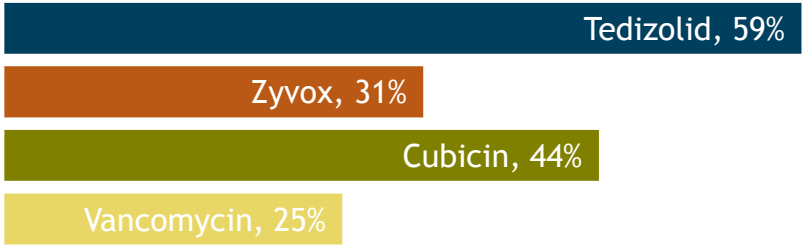
**Has a low frequency of DDI (drug-drug interaction)**




**Does not cause renal and hepatic impairment**

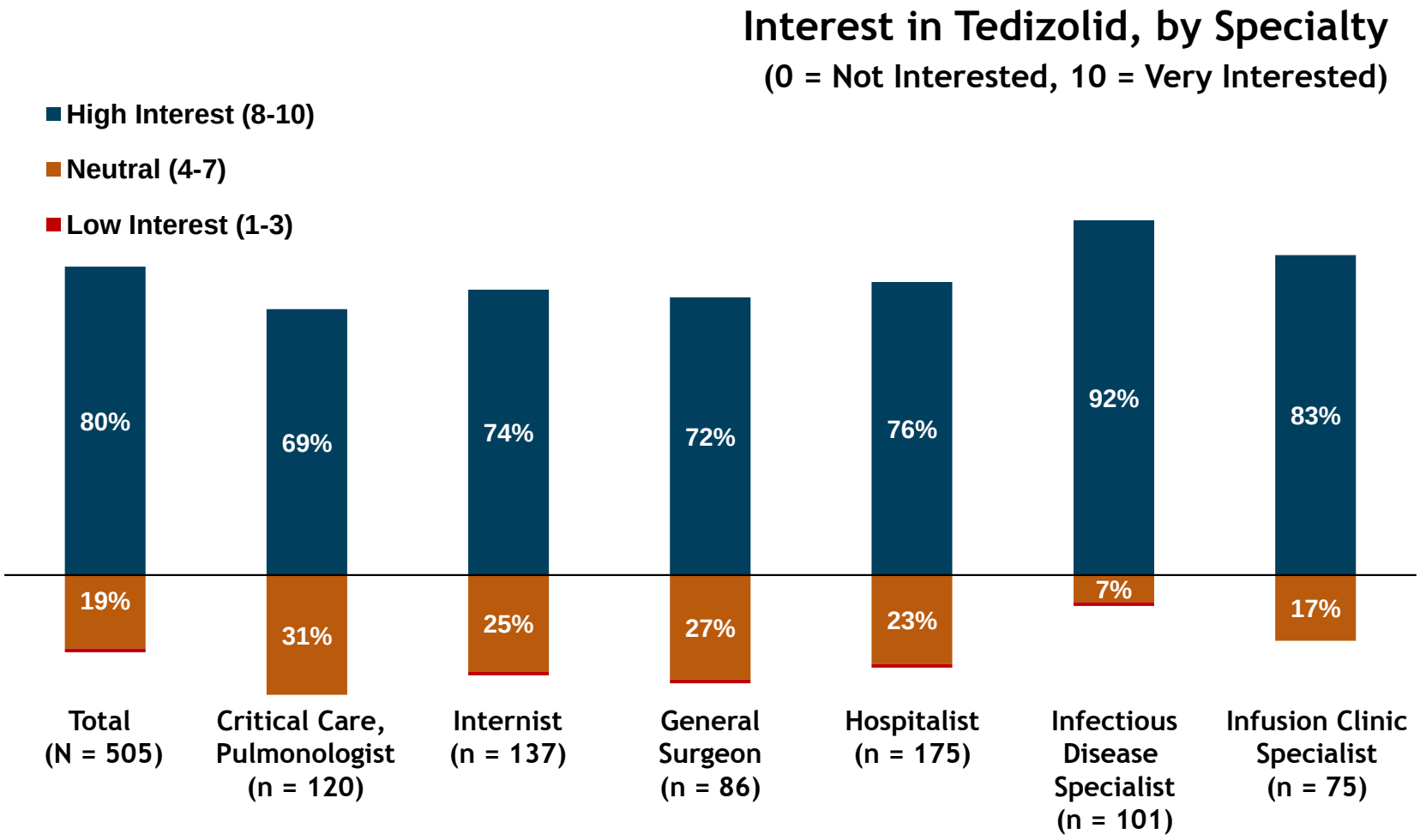



**Has a low frequency of safety/adverse events**




**Efficacy performance ratings among those aware of brand*
*Tedizolid ATU Study, Wave 1 – USA Report, conducted by CMI on behalf of Trius, November 2012, N=505*

# Physician Interest in Tedizolid Strong Across Specialties




Tedizolid ATU Study, Wave 1 – USA Report, conducted by CMI on behalf of Trius, November 2012, N=505
Base: Total respondents
Q8.1 How interesting is tedizolid to you for suspected or confirmed MRSA ABSSSI patients overall? Use a 1 to 10 scale where "1" means "Not at all Interesting" and "10" means "Very Interesting," to indicate your level of interest.

# Upcoming Milestones

- Late breaker presentations at ECCMID conference (submitted for April)
- Detailed data presentations at ICAAC conference (September)
- Advance EU partnership discussions
- NDA Filing (H2 2013)
- Implement pre-commercial activities for potential U.S. launch (H2 2013)
- Initiation of Phase 3 ventilated nosocomial pneumonia study (H2 2013)
- EMA Filing (H1 2014)
- Potential PDUFA date for ABSSSI (mid 2014)