LCP
LIFECYCLE PHARMA

Improving Treatments
Improving Lives

Phase 3 Study Results
Investor Conference

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LCP-TACRO™ OVERVIEW

Improved formulation of tacrolimus based on LCP proprietary MeltDose® technology

- Once-daily dosing
- Improved PK (pharmacokinetics) profile, reducing peak drug concentration
- Lower dose required due to improved absorption
- Not substitutable by generics, providing patients and physicians with consistency

Tacrolimus is the current "gold standard" primary immunosuppressant

- $2B in annual sales of Prograf®/Advagraf® by Astellas
- 90% of transplant patients in the US receive tacrolimus

LCP-Tacro™ offers the potential to supplant Prograf®/Advagraf® as standard therapy

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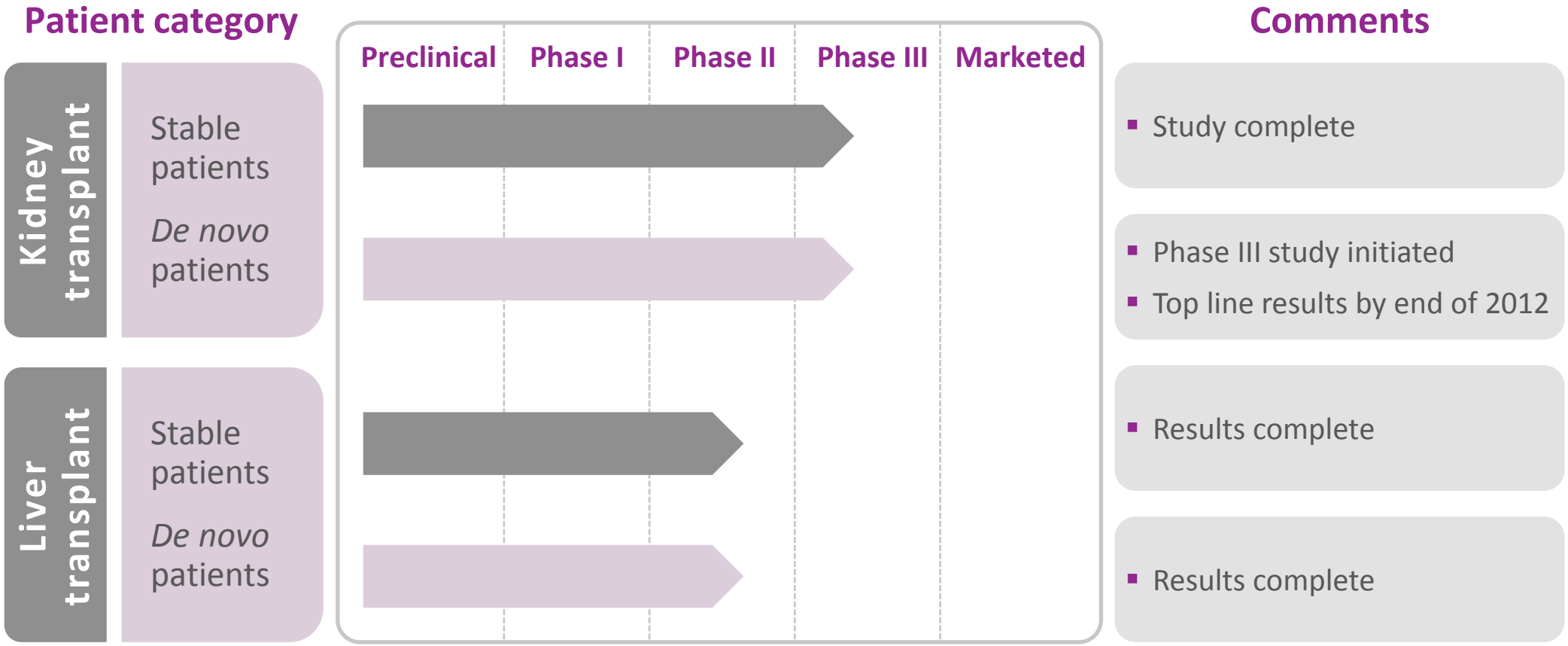
LCP-TACRO™ DEVELOPMENT OVERVIEW



NDA/MAA filing for LCP-Tacro™ tablets is projected for 1Q 2013

DEFINITIONS

- "Efficacy" – Ability to protect the graft against rejection
  - Measured by a regulatory agency composite endpoint that consists of 4 parts
    - Biopsy proven acute rejection
    - Loss of the transplanted organ (return to dialysis or need for another transplant)
    - Death
    - Loss to follow-up – Patient cannot be found
- "Safety" – Adverse events and predefined meaningful changes in laboratory values
- "Biopsy proven acute rejection" (BPAR)
  - An examination of a needle biopsy specimen from a transplanted organ suspected of potential to be in early stage of rejection
    - Early evidence of organ failure (rising creatinine level) leads to needle biopsy of the transplanted kidney
  - Microscopically proven to have immune white blood cells infiltrating the transplanted organ – evidence of early rejection by defined criteria (Banff)

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STUDY 3001 PHASE 3 RESULTS
STABLE "SWITCH" STUDY

3001 DESIGN

- Open-label “switch” study
  - Patients were stable, doing well on Prograf®, and were “switched” in an open-label fashion to either the experimental drug (LCP-Tacro™, at a reduced dose) OR continued therapy with their known drug (Prograf®, at the same dose)
- Primary endpoint
  - Treatment failure “composite”: BPAR, graft loss, death, loss to follow-up
  - Timepoint: Month 12
- Biostatistical planning:
  - Assumption: 6% composite treatment failure rate
  - Noninferiority margin of 9% for the 95% confidence interval
- Geography: US and EU

DEMOGRAPHICS AND BASELINE CHARACTERISTICS

	LCP-Tacro™ (N=163)	Prograf® (N=163)
Age (years)	50.4	50.2
Gender (% male)	71.8	62.6
Race (% black)	22.1	20.9
Time from transplant (years)	2.1	1.8*
Diabetic (%)	37.4	32.5
Prior transplant (%)	13.5	12.3
Renal function (mL/min)	78.74	75.01
Prograf dose at entry (mg/day)	6.09	5.30†

- Population generally well-matched at baseline; slightly higher Prograf® dose at baseline in LCP-Tacro™ group
- Good representation of black patients

P-value between groups: * $p<0.05$ † $p=0.063$

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PATIENT DISPOSITION

	LCP-Tacro™ (N=163)	Prograf® (N=163)
Randomized	100.0%	100.0%
Included in mITT	162 (99.4%)	162 (99.4%)
Discontinued		
– Due to AEs	12 (7.4%)	2 (1.2%)
– Patient decision	6 (3.7%)	3 (1.8%)
– Other	3 (1.8%)	4 (2.5%)

- No consistent pattern to types of events leading to discontinuation

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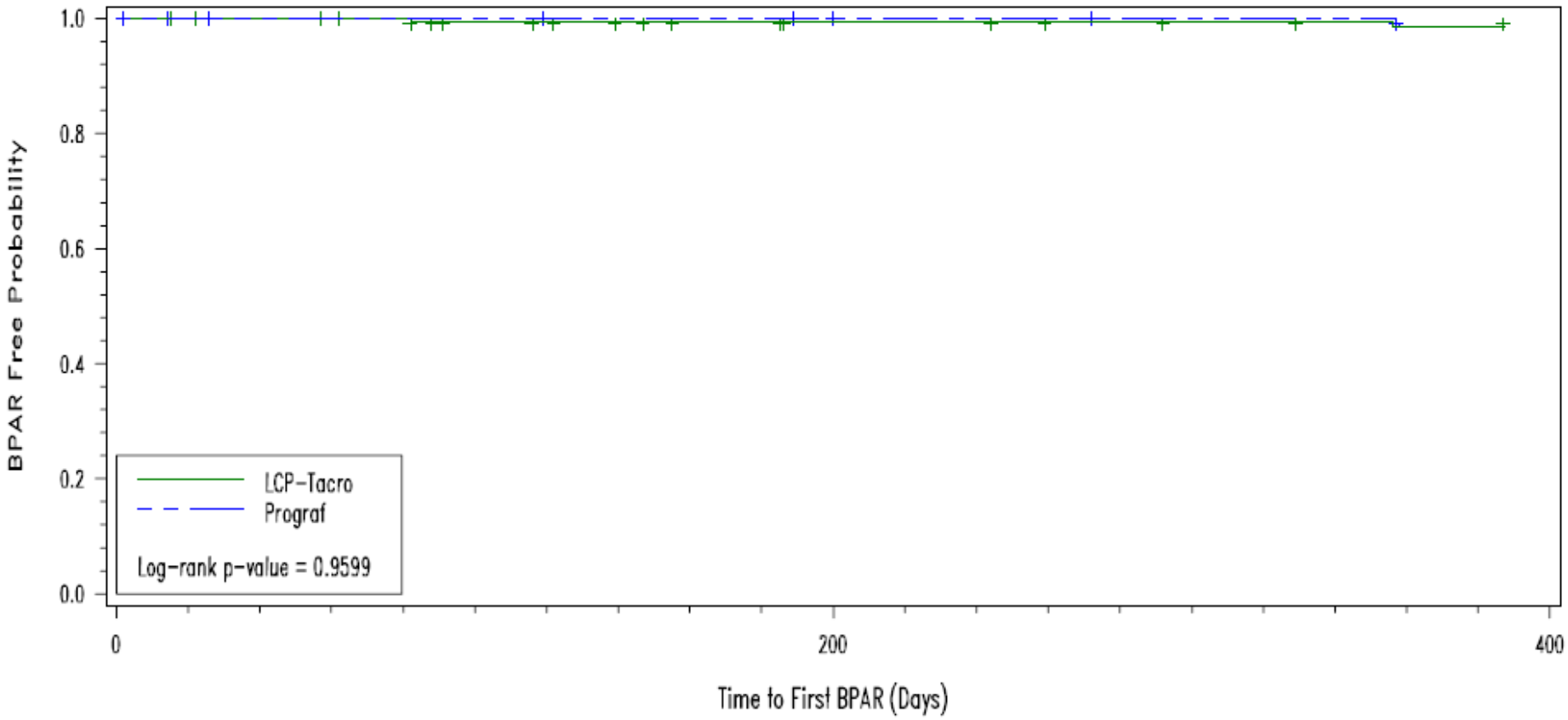
PRIMARY EFFICACY: POSITIVE RESULTS

Primary Efficacy (Local-biopsy reading)

	LCP-Tacro™ (N=162)	Prograf® (N=162)
Biopsy-proven acute rejection	2 (1.2%)	2 (1.2%)
Graft loss	0	0
Death	2 (1.2%)	1 (0.6%)
Lost to follow-up	0	1 (0.6%)
Composite endpoint	**4 (2.5%)**	**4 (2.5%)**
Treatment difference (95% CI)	**0% (-4.2,+4.2)**	

Successful primary outcome:
Upper boundary of confidence interval is less than +9.0%

KAPLAN-MEIER ANALYSIS OF ACUTE REJECTIONS



Very low rate of acute rejections

- Provides ability for physicians to “switch” with confidence from Prograf to LCP-Tacro™, at protocol-specified conversion dose, maintaining good protection of graft

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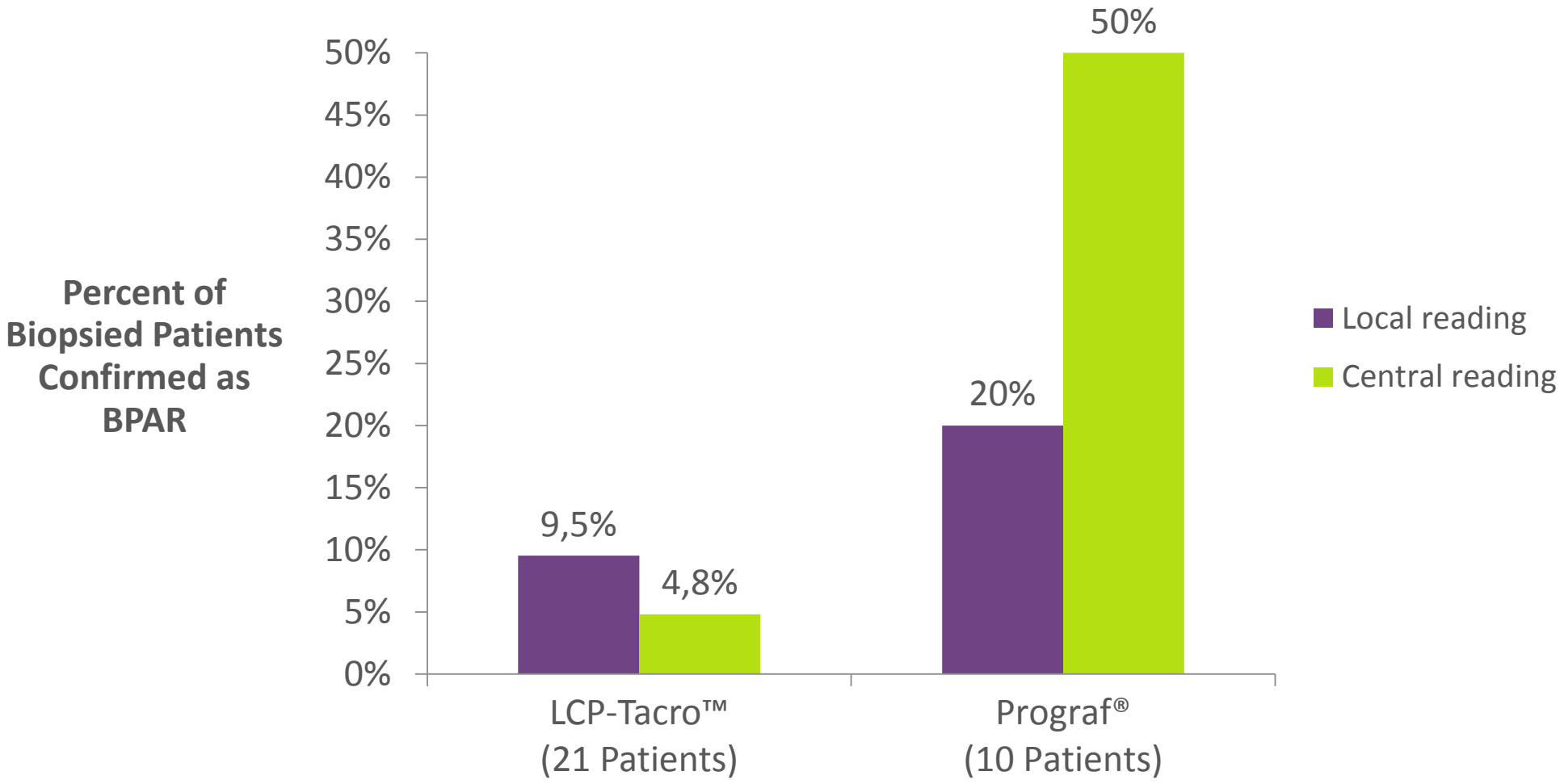
SECONDARY EFFICACY: NUMERICAL TREND TOWARD SUPERIORITY WITH LCP-TACRO™

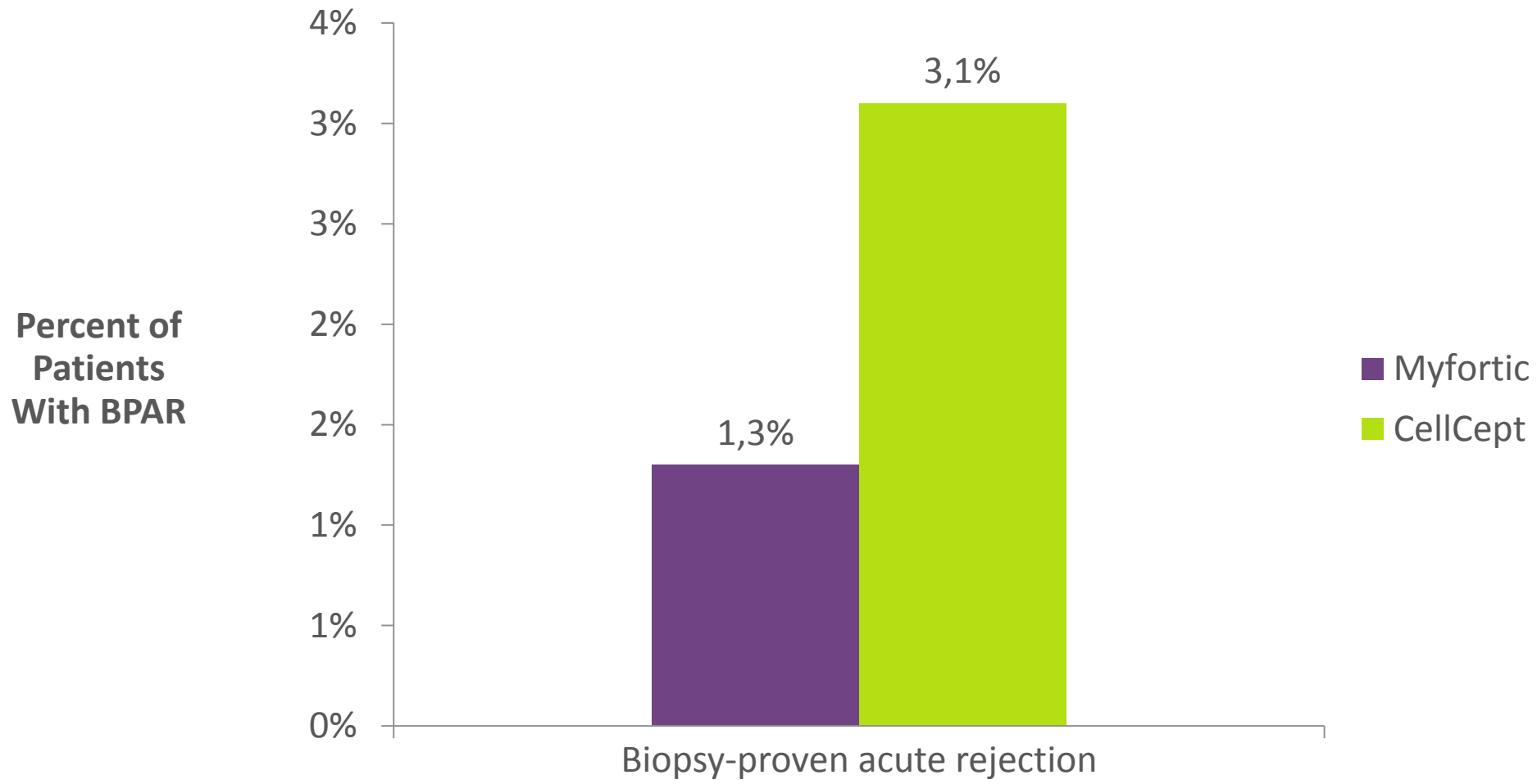
	Secondary Efficacy (Central biopsy reading, all data including follow-up)	
	LCP-Tacro™ (N=162)	Prograf® (N=162)
Biopsy-proven acute rejection*	1 (0.6%)	5 (3.1%)
Graft loss	0	1 (0.6%)
Death	3 (1.9%)	1 (0.6%)
Lost to follow-up	0	1 (0.6%)
Composite endpoint	**4 (2.5%)**	**8 (4.9%)**
Treatment difference (95% CI)	**-2.47% (-7.53,+1.94%)**	

***P*-value for central BPAR: *p*=0.214**

PROPORTION OF BIOPSIED PATIENTS WITH ACUTE REJECTION DETECTED ON BIOPSY



PUTTING RESULTS IN CONTEXT OF LITERATURE: PUBLISHED MYFORTIC "SWITCH" STUDY

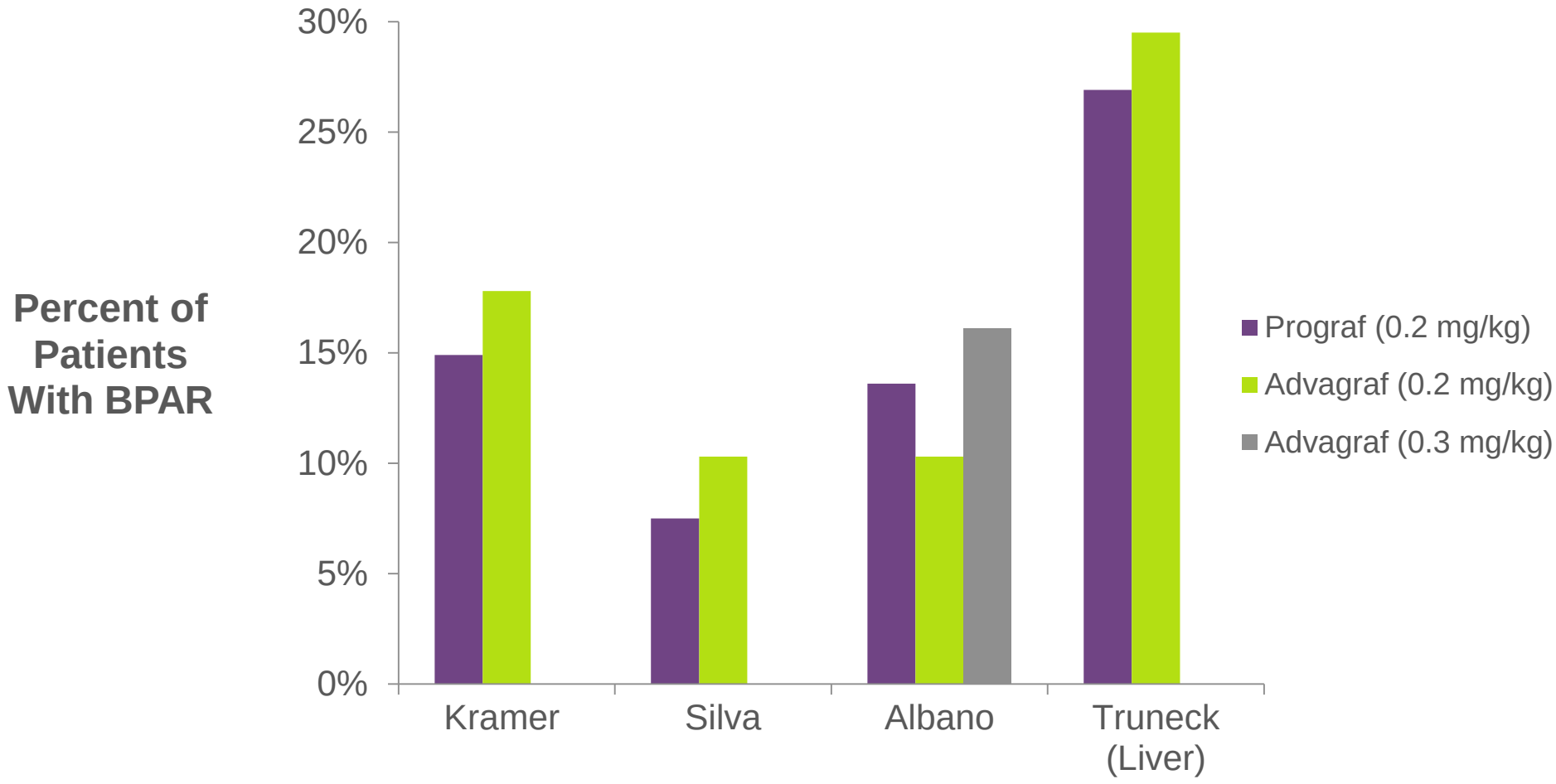


Combination treatment with Myfortic or CellCept + cyclosporine + corticosteroids

Budde, AJT 2003

PUTTING RESULTS IN CONTEXT OF LITERATURE: ADVAGRAF PUBLISHED COMPARISONS TO PROGRAF

4 published Advagraf studies (all *de novo*)



Kramer, AJT 2010; Silva, AJT 2007; Albano, ATC 2011 (abstract); Truneck, AJT 2010

LCP-TACRO OPEN-LABEL "SWITCH" STUDY SAFETY AND TOLERABILITY

	LCP-Tacro™ (N=162)	Prograf® (N=162)
Any adverse event (AE)	83.3%	81.6%
Serious AE	22.2%	16.0%
Drug-related AE	21.6%	13.0%

No significant differences in predefined AEs of interest:

- New-onset diabetes
- Opportunistic infection
- Malignancy
- Prespecified laboratory parameters

Numerically more GI AEs, fewer urinary tract infections

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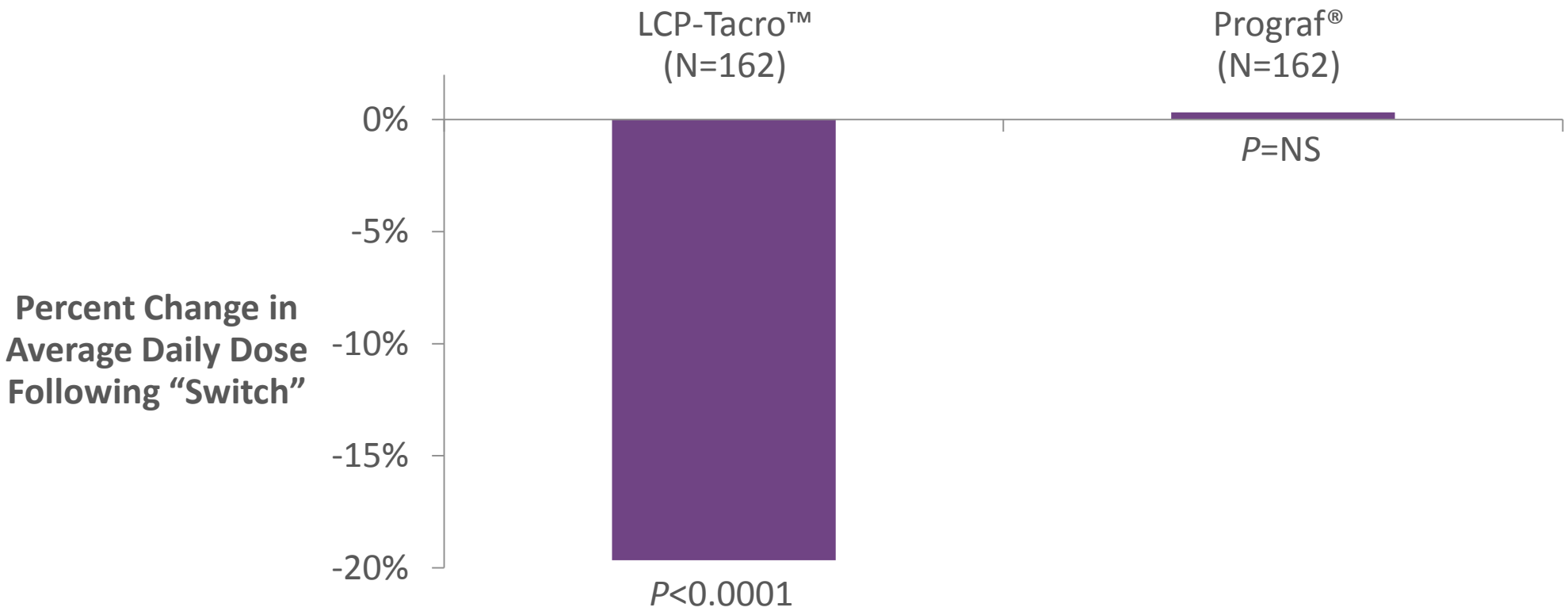
DOSE ADMINISTERED



LCP-Tacro™ enabled a significant reduction in dose

CONCLUSIONS

- Successful Phase 3 results
  - Primary outcome achieved
  - Very low rate of treatment failures in both groups
  - Noninferiority vs Prograf efficacy achieved in the switch setting
    - Protocol-specified NI margin: 9.0%
    - Actual result: 4.2% (well within the required 9% margin)
  - Comparable safety and tolerability to Prograf
- Overall conclusions
  - Successful Phase 3 study, with
    - Once-daily dosing (as opposed to twice-daily), AND
    - Lower dose requirement
  - Evidence that physicians can “switch” successfully from Prograf twice daily to LCP-Tacro™ once daily with confidence in maintaining graft protection
  - Possible trend toward superior efficacy with LCP-Tacro™ by central biopsy results

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LCP UPCOMING MILESTONES

- LCP-Tacro™ is progressing well toward projected registration in US and EU
  - 3001 switch results are positive
    - Results submitted for presentation at upcoming scientific transplant meetings
  - 3002 study is under SPA agreement and enrolling actively
- Additional differentiation clinical study work to be initiated in 2011 along with remaining PK/PD clinical work for registration

LCP-TACRO™ – SUBSTANTIAL COMMERCIAL POTENTIAL

Market

- A $5B market with unmet needs
- Few existing competitors, few compounds in development
- Limited sales force and commercial resources required to promote to this specialty market

Product

- A differentiated product able to attain significant pricing
- Positioned to be the optimized, branded primary immunosuppressant
- Proprietary technology for LCP-Tacro™

Strategy

- Opportunity to commercialize independently or with partner, regionally or globally
- ~20 sales reps needed to cover US market

LCP can choose to commercialize LCP-Tacro™ independently or through a partner

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UPCOMING EVENTS

- EGM 07-July-2011
  - Ed Penhoet nominated as Director
    - Chiron – Co-founder, President, and CEO
    - Director in Alta Partners
    - Member of Board of Directors: ChemoCentryx, Immune Design, Metabolex, Scynexis, and ZymoGenetics
    - Member of President Obama's Council of Advisors on Science and Technology
  - Company name change to Veloxis Pharmaceuticals A/S

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Q & A

Thank you for your attention