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**CAPACITY Results Conference Call**  
February 3, 2009

Innovative Medicines for Pulmonology and Hepatology

## Legal Disclaimer

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**This presentation contains forward looking statements pertaining to the ongoing discovery, development and commercialization of InterMune's drug candidates and products. The Company's actual results may differ from the claims discussed in these forward looking statements. For a discussion of our risk factors, please refer to InterMune's disclosure documents filed with the SEC, including our 10-K and 10-Q filings.**

## InterMune Participants

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- » **Dan Welch, Chairman, CEO and President**
- » **Dr. Bill Bradford, Sr. Vice President, Clinical Science and Biometrics**
- » **Dr. Steve Porter, Chief Medical Officer**
- » **Dr. Paul Noble, Duke University and CAPACITY protocol co-chair**



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**Dan Welch**  
Chairman, CEO  
and President

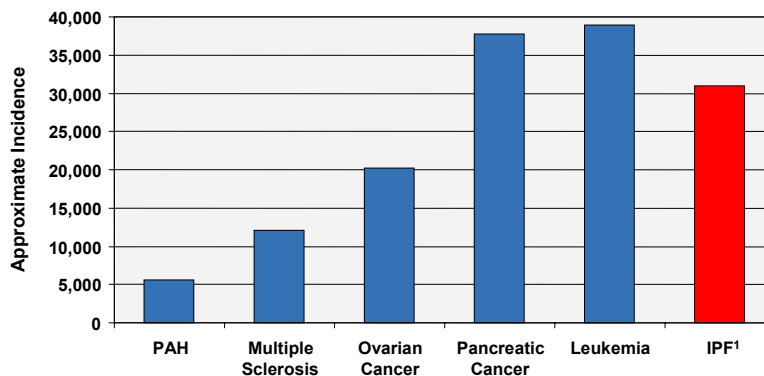


## CAPACITY Phase 3 Results

1. We are pleased by the overall safety and efficacy profile of pirfenidone observed in CAPACITY. CAPACITY 2 demonstrated a statistically significant effect on the primary endpoint and on several key secondary endpoints. Although CAPACITY 1 did not achieve statistical significance on its primary endpoint, results were supportive of the CAPACITY 2 results
2. The treatment effect observed in two Phase 3 CAPACITY studies is consistent with a third Phase 3 study conducted by Shionogi, which formed the basis of approval of pirfenidone for IPF in Japan
3. The treatment effect comes without a significant increased risk for the patient in terms of safety or tolerability
4. The unmet need for new treatments in IPF is among the most urgent in medicine today



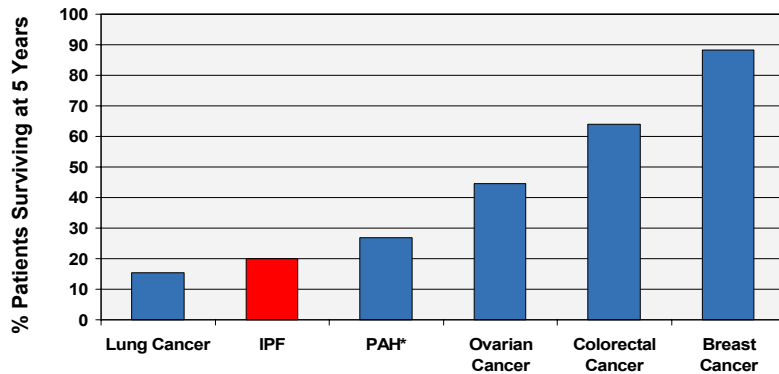
## IPF Incidence Rate Compared to Other Serious Diseases



<sup>1</sup>Weycker D, et al. *Prevalence, Incidence, and Economic Costs of Idiopathic Pulmonary Fibrosis*. CHEST 2002, San Diego, California, November 2-7, 2002. All others: *Incidence and Prevalence Database*, Timely Data Resources, Inc.



## IPF Survival is Low – Worse Than Most Cancers



**The lack of an approved therapy for IPF represents a critical unmet medical need**



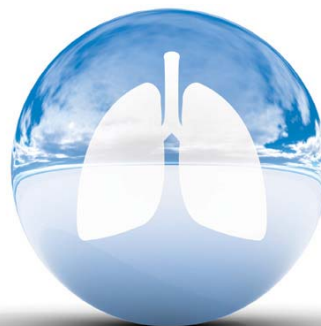
## Collective Phase 3 Results Support Preparation of an NDA and an MAA

- » **An overall pirfenidone treatment effect in IPF patients has now been observed in three Phase 3 studies**
  - Two Phase 3 CAPACITY studies (one met primary endpoint)
  - One Shionogi Phase 3 study (met primary endpoint)
- » **Pirfenidone appears to be safe and generally well tolerated in these IPF studies**
- » **Urgent unmet medical need – no approved medicines for IPF**
- » **NDA and MAA submissions as soon as possible**



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**Dr. Bill Bradford**  
SVP, Clinical Science  
and Biometrics



## Conclusions

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- » CAPACITY 2 demonstrated a robust and statistically significant treatment effect on the primary endpoint and key secondary endpoints
- » CAPACITY 1 did not achieve statistical significance on its primary endpoint, but did provide supportive evidence of a favorable treatment effect of pirfenidone
- » Pirfenidone was safe and generally well-tolerated
- » Excellent study conduct enabled delivery of high quality data
- » Efficacy and safety data from two Phase 3 CAPACITY studies and one Phase 3 Shionogi study, in context of an urgent unmet medical need for new medicines to treat IPF, suggest pirfenidone may play a meaningful role in the management of patients with IPF

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## Design of Phase 3 CAPACITY Program

- » Two concurrent, multi-national trials
- » Total 779 patients
- » CAPACITY 1—344 patients PFD 2403mg: Placebo (1:1)
- » CAPACITY 2—435 patients PFD 2403mg: Placebo: PFD 1197mg (2:2:1)
- » Primary endpoint: Change in percent predicted Forced Vital Capacity (FVC) at 72 weeks (Rank ANCOVA)
- » Secondary endpoints
  - Measures of lung function, exercise tolerance, patient-reported outcomes, etc.
  - Primary analysis of secondary endpoints to be pooled (2403mg vs. placebo) if primary endpoint in both studies is met
- » Patients continue on study until last enrolled patient completes Week 72



## Demographics and Baseline Characteristics

	CAPACITY 1		CAPACITY 2	
	PFD (N=171)	Placebo (N=173)	PFD (N=174)	Placebo (N=174)
<b>Demographics</b>				
Median Age (yrs.)	67	67	66	67
Male	72%	72%	68%	74%
<b>Baseline Characteristics</b>				
HRCT Definite IPF	88%	91%	91%	94%
Surgical Lung Biopsy	55%	54%	49%	49%
Median % predicted FVC	74.5%	70.3%	73.0%	73.6%
Oxygen use	28%	28%	17%	14%
Median 6MWT distance (m)	381	396	421	416



## Patient Disposition

	CAPACITY 1		CAPACITY 2		
	PFD 2403	Placebo	PFD 1197	PFD 2403	Placebo
Randomized	171	173	87	174	174
Completed treatment*	82%	90%	85%	83%	90%
AE leading to treatment discontinuation	14%	8%	13%	12%	8%
Completed Study*	92%	95%	94%	93%	95%

\*Death and lung-transplant patients classified as completers



## Primary Efficacy Analysis: Change in Percent Predicted FVC at Week 72

Week	CAPACITY 1				CAPACITY 2			
	LS Mean Change		Relative reduction	Rank ANCOVA P value	LS Mean Change		Relative reduction	Rank ANCOVA P value
	PFD	Placebo			PFD	Placebo		
12	-1.22	-1.32	7%	0.021	-1.10	-2.26	51%	0.061
24	-1.32	-3.82	65%	<.001	-1.18	-3.04	61%	0.014
36	-1.91	-3.86	50%	0.011	-2.25	-5.30	58%	<.001
48	-3.87	-5.43	29%	0.005	-3.64	-6.70	46%	<.001
60	-5.50	-6.23	12%	0.172	-5.23	-7.93	34%	<.001
72	-6.49	-7.23	10%	0.501	-6.49	-9.55	32%	0.001



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## Overall Treatment Effect on FVC based on Repeated Measures Analysis (Exploratory)

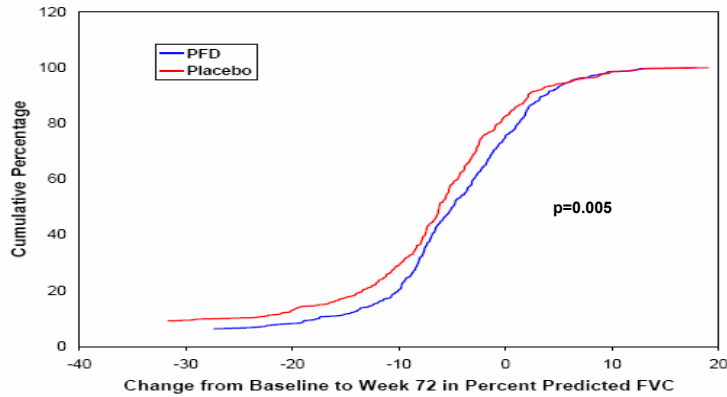
- » Repeated measures (RM) analysis conducted on FVC data ranked per primary endpoint analysis at each assessment time point (i.e. 12, 24, 36 weeks, etc.)
- » Analysis interrogates treatment effect over full duration of study as opposed to Week 72 alone

	CAPACITY 1	CAPACITY 2	Pooled
Overall RM P value	0.004	0.001	< .001

- » Provides further evidence of a positive pirfenidone treatment effect over the duration of the study period and the consistency of the treatment effect between studies



## Ogive Plot and Rank ANCOVA of Pooled Primary Endpoint Data at Week 72 (Exploratory)



» Ogive plot illustrates a positive pirfenidone treatment effect across the spectrum of FVC change at Week 72



## Statistical Outcomes (P values) for Efficacy Endpoints

	CAPACITY 1	CAPACITY 2	Pooled
<b>Primary Endpoint: FVC Change</b>			
Rank ANCOVA at Week 72	0.501	0.001	0.005
Overall repeated measures	0.004	0.001	< .001
<b>Secondary Endpoints</b>			
Time to worsening IPF	0.248	0.515	0.204
Progression-free survival	0.355	0.023	0.029
Categorical FVC change	0.440	0.001	0.003
6MWT distance change	0.001	0.171	0.001
Dyspnea (UCSD SOBQ) change	0.600	0.500	0.400
DL <sub>CO</sub> change	0.990	0.145	0.301
6MWT worst SpO <sub>2</sub> change	0.890	0.087	0.261
HRCT fibrosis change	0.894	NA	NA
<b>Exploratory Endpoint</b>			
Survival time	0.872	0.191	0.315



## Secondary Endpoint: FVC Change at Week 72 by Category

Patients (%)	CAPACITY 1		CAPACITY 2	
	PFD (N=171)	Placebo (N=173)	PFD (N=174)	Placebo (N=174)
Severe decline $\geq 20\%$	12%	13%	8%	16%
Moderate decline: $\geq 10\%$ to $20\%$	11%	13%	12%	19%
Mild decline: $\geq 0\%$ to $<10\%$	52%	51%	56%	52%
Mild Improvement: $>0\%$ to $<10\%$	24%	19%	23%	14%
Moderate Improvement: $\geq 10\%$	2%	3%	1%	0
P value vs. placebo (CMH row mean scores)	0.440		0.001	



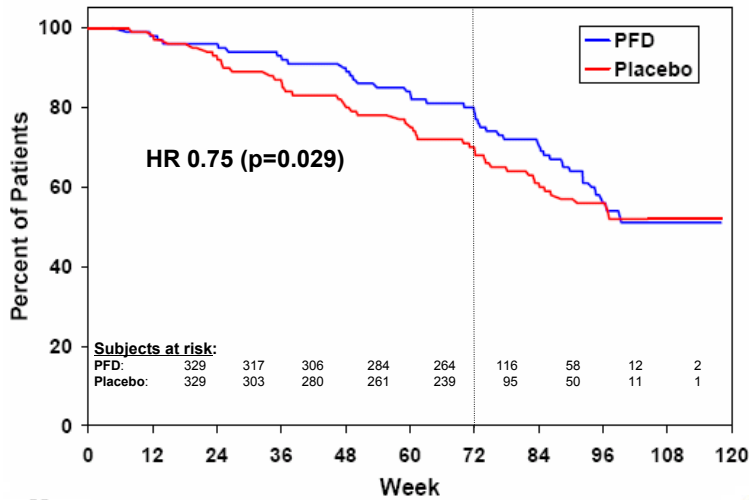
## Progression-Free Survival (PFS)\*

	CAPACITY 1		CAPACITY 2	
	PFD (N=171)	Placebo (N=173)	PFD (N=174)	Placebo (N=174)
Events	32%	35%	26%	36%
25 <sup>th</sup> percentile (weeks)	72.3	61.3	77.6	50.3
Hazard Ratio	0.84		0.65	
P value (log rank)	0.355		0.023	

\* Defined as Time to Death or Disease Progression  
( $\geq 10\%$  decrease in FVC or  $\geq 15\%$  decrease in DL<sub>CO</sub>)



## PFS Analysis of Pooled Data (Exploratory)



## 6MWT Distance (meters): Change at Week 72

Week	CAPACITY 1				CAPACITY 2			
	Mean Change		Relative reduction	Rank ANCOVA P value	Mean Change		Relative reduction	Rank ANCOVA P value
	PFD	Placebo			PFD	Placebo		
12	-8	-9	8%	0.975	-8	-15	46%	0.690
24	-8	-28	72%	0.038	-14	-31	54%	0.421
36	-16	-37	56%	0.044	-17	-34	49%	0.468
48	-24	-45	48%	0.023	-35	-53	34%	0.068
60	-32	-56	43%	0.014	-44	-66	34%	0.059
72	-45	-77	41%	0.001	-60	-77	21%	0.171

## Overall Survival (Pre-specified Exploratory Endpoint)

	CAPACITY 1		CAPACITY 2		Pooled	
	PFD (N=171)	Placebo (N=173)	PFD (N=174)	Placebo (N=174)	PFD	Placebo
Deaths	9.4%	9.8%	6.3%	9.8%	7.8%	9.8%
Hazard Ratio	0.94		0.61		0.78	
P value vs. placebo (log rank)	0.872		0.191		0.315	



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HRCT fibrosis change	0.894	NA	NA
<b>Exploratory Endpoint</b>			
Survival time	0.872	0.191	0.315



## Summary of Treatment Emergent Adverse Events (AEs)

Patients	CAPACITY 1		CAPACITY 2		
	PFD 2403 (N=171)	Placebo (N=173)	PFD 1197 (N=87)	PFD 2403 (N=174)	Placebo (N=174)
<b>With at least one AE</b>	<b>99%</b>	<b>98%</b>	<b>99%</b>	<b>98%</b>	<b>97%</b>
≥ 1 Grade 3	30%	24%	29%	37%	29%
≥ 1 Grade 4	6%	9%	8%	7%	9%
<b>With at least one serious AE</b>	<b>31%</b>	<b>30%</b>	<b>32%</b>	<b>35%</b>	<b>33%</b>
<b>Death</b>	<b>11%</b>	<b>10%</b>	<b>12%</b>	<b>8%</b>	<b>12%</b>



## Common AEs with Incidence ≥1.5 Times in the Pirfenidone vs. Placebo Groups

Patients (%)	CAPACITY 1		CAPACITY 2	
	PFD (N=171)	Placebo (N=173)	PFD (N=174)	Placebo (N=174)
Nausea	38	16	35	18
Rash	34	13	31	10
Fatigue	33	20	28	21
Diarrhea	33	21	25	17
Dyspepsia	21	6	17	9
Dizziness	18	10	19	10
Gastro-esophageal Reflux	6	7	15	8
Photosensitivity Reaction	10	2	14	1
Vomiting	14	5	14	4
Insomnia	7	6	13	7
Arthralgia	9	6	12	8
Anorexia	11	4	11	4
Urinary Tract Infection	9	12	11	5
Abdominal Distension	11	5	9	7

Common AEs are defined as occurring ≥10% of pirfenidone 2403 mg patients in either study



## Exploration of Dose Response in CAPACITY

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- » A low-dose pirfenidone group (1197mg; n=87) included in CAPACITY 2 for descriptive purposes
- » Efficacy outcome measures showed a demonstrable, but more modest treatment effect compared to the high-dose group
- » Low-dose pirfenidone was safe and generally well tolerated with overall fewer side effects than the high-dose group
- » Dose response observations support overall efficacy and safety conclusions



## CAPACITY Results Consistent with Shionogi Phase 3 Study

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- » Randomized, double-blind, placebo-controlled study conducted in Japan
- » 2:2:1 randomization: PFD 1800 mg/d: Placebo: PFD 1200 mg/d
- » 267 patients with confident IPF diagnosis
- » Primary endpoint VC change at 52 weeks (p=0.042)
  - 44% relative reduction in VC decline
- » Key secondary endpoint: PFS (p=0.028)
- » Safety: safe and generally well tolerated
  - Pirfenidone associated with rash and GI AEs



## Conclusions

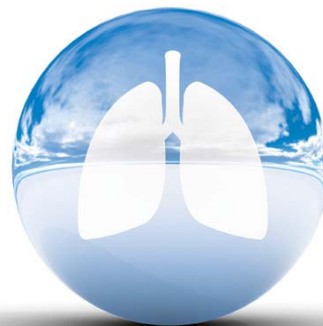
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- » CAPACITY 2 demonstrated a robust and statistically significant treatment effect on the primary endpoint and key secondary endpoints
- » CAPACITY 1 did not achieve statistical significance on its primary endpoint, but did provide supportive evidence of a favorable treatment effect of pirfenidone
- » Pirfenidone was safe and generally well-tolerated
- » Excellent study conduct enabled delivery of high quality data
- » Efficacy and safety data from two Phase 3 CAPACITY studies and one Phase 3 Shionogi study, in context of an urgent unmet medical need for new medicines to treat IPF, suggest pirfenidone may play a meaningful role in the management of patients with IPF



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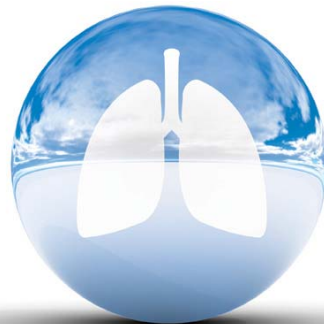
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## Summary and Next Steps

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- » **Three Phase 3 Studies of pirfenidone in IPF**
  - Two met primary FVC/VC endpoint (CAPACITY 2, Shionogi)
  - Favorable treatment effect in all three studies
  - Safe and generally well-tolerated
- » **Urgent unmet medical need**
- » **NDA and MAA submissions as soon as possible**
- » **Begin partnering discussions with several interested companies**
- » **Continue aggressive development of ITMN-191 (R7227)**
- » **2009 Financial and Project Guidance 2/09**



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