FDANEWS/ CenterWatch

Integrating Expanded Access into Clinical Development of New Medicines

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THE WEST COAST SYMPOSIUM ON EXPANDED ACCESS

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COMMERCIAL ASSESSMENT OF FEASIBILITY AND PROGRAM GOALS

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Points to discuss:

- Pre or post filing access?
- Access prior to approval in at least one country?
- Charging for access
- Pricing
- Availability of IP and/or commercial drug
- Program closure
- Transition of patients to country specific commercial product

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- Access prior to approval in at least one country?
- Country specific regulations
- May not allow charging until first approval
- IP switch to commercial product
- Charging impact on pricing
- When? Management of existing patients?

THANK YOU

QUESTIONS?