

Tentative Plan for the Public Forum during Kamakura Live Demonstration Course 2005

A) What has been decided so far?

- (1) Goals or Objectives of the Forum:
 - (a) Public education on modern PCI, especially on DES
 - (b) Public education on what is necessary to get the truth in clinical medicine (the importance of clinical trial)
 - (c) Public education on how the Government will approve new therapeutic modalities based on good clinical trials
 - (d) Public education that the development of medicine is not only based on medical societies, manufacturers or Government activities but also on the active engagements on it by patients
 - (e) This is absolutely not planned to blame anybody or any organizations.
 - (f) This is planned for the next steps - What are the current problems? Where we have to go?
- (2) Date, Time, Venue, etc:
 - (a) December 15 THURSDAY, 2005
 - (b) 13:00 - 18:00 or 14:00 - 17:00
 - (c) Hamagin Hall Via Male, Yokohama, Japan (beautiful place)
 - (d) 500 relaxed seats available with stage, screen and projectors
 - (e) Simultaneous Japanese-English translation available
- (3) Organizing Body:
 - (a) NPO TRI International Network (certified by Kanagawa Prefectural Government)
 - (b) the Japanese Society of Interventional Cardiology (JSIC)
 - (c) the Japanese Association of Cardiac Catheter Therapeutics (JACCT)
- (4) Planned Participants:
 - (a) General people. However, we are planning to invite patients from our outpatient clinics preferentially
 - (b) General practitioners. We will send official pamphlets to local practitioners' societies
 - (c) Company persons
- (5) Chairpersons:
 - (a) Dr. Tohyama from Kanagawa Prefectural Center of Circulation and Pulmonary

Diseases with Dr. Kato from Yokohama Rosai Hospital

(b) Mitch and I

(6) Planned Discussants:

- (a) One actual patient who had previous therapy in oversea country, which has not been approved in Japan. I can nominate the patient.
- (b) Physicians from our team: Kazu, Mitch, I, Dr. Tohyama, Dr. Kato, ---
- (c) A physician who can talk about the problems surrounding an anti-neoplastic drug IRESSA (EGFR Tyrokinase Inhibitor by Astro-Zeneka). What were the problems in their clinical trials? What were the problems made by physicians after the Government approval (Off-Label Use)? etc
- (d) I would strongly request one or two officials from US-FDA
- (e) I would strongly ask Dr. Tsukano or other one or two officials from Japanese MHLW
- (f) I would strongly hope personnel from PMDA, Japan, especially Dr. Kohji Ikeda and Dr. Katsumi Kinoshita

B) Tentative Schedule of the Public Forum:

- (1) The 1st part:
 - (a) General education on PCI and DES
 - (b) Brief introduction and education on how new modalities are introduced in medical fields (maybe by I or Kazu)
- (2) The 2nd part:
 - (a) Introduction of the importance of good clinical trials (by Mitch)
 - (b) Education or introduction of the Government approval system by MHLW and PMDA
 - (c) Education or introduction of the Government approval system by FDA
 - (d) Brief introduction of HBD
- (3) The 3rd part:
 - (a) Talk on her own experience by the patient, who went to Seoul, Korea to have brachytherapy for the recurrent in-stent restenosis.
 - (b) Lecture on the problems of IRESSA by a physician (not blaming the Government approval process, but pointing out the problems within clinical trials or off-label use)
- (4) The last part - Panel Discussion:
 - (a) How we have to do good clinical trials?
 - (b) How HBD activities are important for good clinical trials?

(c) What we have to do for the next steps?

C) What would be requested to Kazu and Mitch from NPO?

- (1) Kazu! Could you advise me when or how I could contact with Dr. Tsukano in MHLW?
Or Can I make an e-mail contact with Dr. Tsukano (I know his e-mail address through his business card)? How I could negotiate with PMDA?
- (2) Kazu! Could you recommend some physicians who can talk about IRESSA adequately?
- (3) Kazu! Could you negotiate any difficult problems, which may happen on the process of making this Public Forum? I really need your kind support and help.
- (4) Mitch! Could you kindly invite FDA officials? Could you make sure?
- (5) Mitch! Could you provide good impression on the Public Forum to Government sides of both Japan and USA?
- (6) Mitch! Could you make any advises to us?

D) What has to be clarified?

- (1) We have to print, circulate or deliver the pamphlets on this Public Forum as soon as possible. Can we use the names of Kazu and Mitch printed on the pamphlet?
- (2) Can we use the sentence as “People from MHLW”, “People from PMDA” and “People from FDA”?
- (3) Since this is the activity by NPO, we are not planning to provide any honorarium to the discussants. Is this principle adequate?

E) What would be the next time frame?

- (1) Since we have only 2 months ++, I would print the official pamphlet by October 22nd.
- (2) I would have definite appointments for participation by Government people by the end of October.