



# COURAGE Chronicle

Courage Chronicle

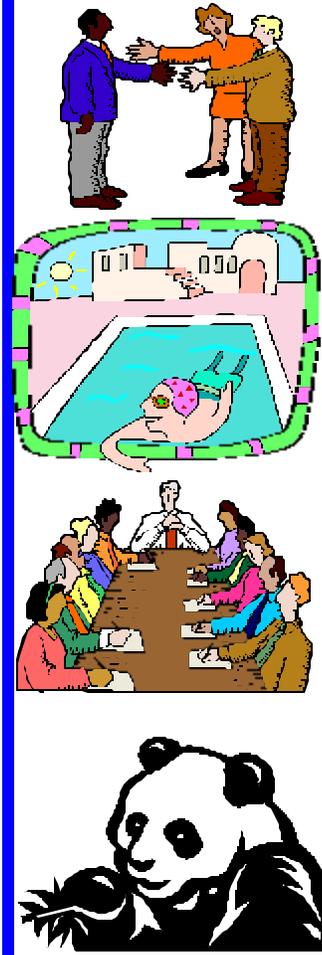
January 2000

## Annual Meeting 2000 in San Diego

24th - 26th of January

The Year 2000 Annual Meeting of the COURAGE Trial will be held at the Hanalei Hotel in Mission Valley, San Diego. This "lush, tropical setting" will provide an opportunity for COURAGE investigators to become (re)acquainted with each other and to discuss and resolve some issues concerning the implementation of the protocol. To this end we are setting up a session on Monday afternoon designed for the new coordinators (**bring your Pentablets !**); this session will also provide a nice review of the Pentablet for those who are interested. After a general session on Tuesday morning, we will spend the rest of Tuesday and part of Wednesday clarifying the CRFs and core lab requirements, as well as discussing the counseling of patients on risk factor reduction (especially exercise) and follow-up procedures.

Connections to the Hanalei Hotel (619-297-1101) from the airport can be made by cab (for \$15.00, up to five people) or by Cloud 9 Shuttle (about \$9.00/person). The hotel provides free shuttle service to Old Town, Fashion Valley (a mall), and the Riverwalk Golf Course. Come prepared to work hard, and then to take advantage of the excellent recreational opportunities offered at the hotel (heated outdoor pool, whirlpool spa, fitness center, etc.) and in the San Diego area, such as Old Town and



## COURAGE CASE OF THE MONTH: Randomization of a Higher-Risk Patient.

RR, a 68 year-old male with a 20-year history of hypertension, diabetes mellitus since 1997 and a two-month history of classic exertional angina, presented in mid-August 1999 with a normal resting ECG. During a Bruce Exercise treadmill test, the patient developed a two mm ST horizontal depression in V5 and V6 at six minutes of exercise. His 201-thallium scintigraphy showed reversible anteroseptal and inferior wall ischemia. On coronary angiography there was an 80% ostial LAD lesion and an 80% mid-LAD lesion, as well as an 80% left circumflex lesion at the ostia of the obtuse marginal branch, and an RCA lesion of 60%. The LVEF was 67%. His BP was 138/83 mm Hg; pertinent lab values were a TC of 188 mg/dl, an LDL of 120 mg/dl, an HDL of 41 mg/dl, a TG of 135 mg/dl, and an HgA1C of 5.6%.

The patient was randomized to Aggressive Medical Therapy without Intervention, including 325 mg ASA daily, 10 mg of amlodipine daily, 100 mg of metoprolol-XL daily, 20 mg of simvastatin daily, and 10 mg of lisinopril BID.

At three months he is asymptomatic, exercises daily by walking and swimming for 20 to 30 minutes each. His BP is 108/60 mm Hg, his TC is 128 mg/dl, with an HDL of 41 mg/dl and an LDL of 69 mg/dl and an HgA1C of 5.3%.

Thus this patient with three-vessel CAD has done well with Aggressive Medical Therapy only.

Case contributed by Robert A. O'Rourke, M.D.

### Use of COURAGE Study Drugs

Although it is not mandated, the COURAGE Leadership strongly encourages sites to use the COURAGE study drugs provided even if these drugs are not currently on their formulary. These drugs have been donated by multiple sponsors to provide cost savings to the participating sites, to encourage patient compliance (since the drugs being provided are dosed once daily) and to provide some degree of standardized care across sites.

Please contact a member of the COURAGE Leadership if this presents a problem at your site.

### Aggrastat® Usage

Aggrastat® (Tirofiban HCl), in combination with heparin, is indicated for patients undergoing PTCA. This is one of several drugs that Merck & Co. has provided for our study. Your Merck Representative can provide you with information concerning the proper use of this agent.

We have received a few questions about the Aggrastat® vials that were shipped to each participating site. In order to expedite the initial shipment of Aggrastat® for our study, Merck took these vials from their clinical supplies and as a result these vials were not labeled with their commercial labeling. The vials provided to PCC were in fact unlabeled. Prior to shipping we placed each vial inside a plastic bag that contained the required labeling information.

Lack of an expiration date on the label was also questioned by one of the sites. The bar code on the bag containing the Aggrastat® vial contains the lot number (#0625288) and repass date (06/09/2000) for this drug. Clinical supplies usually are assigned repass dates rather than expiration dates. An expiration date seldom if ever is extended; however, a repass date is routinely extended based upon review of ongoing accelerated stability studies for that drug. PCC will carefully monitor this repass date and will notify sites when this drug has reached its expiration date. Prior to reaching this expiration date, PCC will automatically send a replacement shipment of Aggrastat® to each site. In the future, it is our understanding that Merck will be providing us with commercially labeled product. This labeling will include the expiration date.



### PATIENT ENROLLMENT UPDATE

671	Audie Murphy VAMC – San Antonio	34
506	Ann Arbor VA Medical Center	21
580	Houston VA Medical Center	19
558	Durham VA Medical Center	17
202	London Health Sciences Centre	14
203	Montreal Heart Institute	12
308	Mid America Heart Institute	12
598	John C. McClellan VA – Little Rock	9
663	Seattle VA Medical Center	8
210	The Toronto Hospital	7
306	Mayo Clinic	7
501	Albuquerque VA Medical Center	7
596	Lexington VA Medical Center	7
200	Foothills Hospital	6
209	Sunnybrook & Women’s College HSC	5
304	Emory University Hospital	5
311	SUNY Health Science Center at Syracuse	5
312	University of Michigan Medical Center	5
313	University of Oklahoma	5
205	Queen Elizabeth II HSC	4
302	Cleveland Clinic	4
508	Atlanta VA Medical Center	4
584	Iowa City VA Medical Center	4
626	Nashville VA Medical Center	4
630	New York VA Medical Center	4
201	Hamilton General Hospital, McMaster Clinic	3
207	St. Paul’s Hospital	2
211	University of Alberta Hospital	2
301	Boston Medical Center	2
208	Sudbury Memorial Hospital	1
300	Barnes-Jewish Hospital	1
307	Christiana Care Health Systems	1

**Total Patients as of 01/10/00: 241**

### Preparing for San Diego!

Coordinators can help ensure that our Annual Meeting answers their needs and promotes the eventual success of the COURAGE Trial by coming prepared to discuss the problems they have encountered in enrolling patients and completing the data forms. So gather up all your questions and note any parts of the Forms that aren’t clear. We are allowing ample time to clear up any difficulties you may be having with



**Please complete and fax your drug inventory reports to the PCC at least every two weeks.**